

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF FLORIDA
3 WEST PALM BEACH DIVISION

4 CASE NO. 20-md-02924-ROSENBERG

5 **IN RE: ZANTAC (RANITIDINE)** .
6 **PRODUCTS LIABILITY** . West Palm Beach, FL
7 **LITIGATION.** . December 15, 2020
8 .
9 .

10 MOTIONS TO DISMISS HEARING (through Zoom)
11 BEFORE THE HONORABLE ROBIN L. ROSENBERG
12 UNITED STATES DISTRICT JUDGE

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1 *THE COURT:* Good morning, everyone. We are here for
2 the second day of hearings in the Motions to Dismiss that have
3 been filed in In Re: Zantac Products Liability Litigation, MDL
4 number 2924.

5 A couple of matters I want to take up first. For all
6 presenters, following your presentation, if you would kindly
7 email your presentation if you have written it out, I suspect
8 most of you have, to Ms. Stipes, Pauline Stipes, she is our
9 court reporter. Her email address is
10 pauline_stipes@flsd.uscourts.gov.

11 The reason for that is, while she, of course, is
12 transcribing only that which is said in your presentations, and
13 certainly is not relying upon your written presentations
14 because you may have varied from it, if there is a question she
15 has about the pronunciation of a name, or a case, reference to
16 your presentation will aid her to ensure she will put together
17 the most perfect record possible. Those are her standards and
18 those are my standards and I am sure that is what each of you
19 want as well.

20 We don't need them before your presentation, but after
21 you have given your presentation, if you email them to
22 Mrs. Stipes and this will aid her so there are as few
23 unintelligible or inaudible references in the record as
24 possible. Zoom has worked very well for all of us during this
25 litigation, but it is not perfect.

1 When attorneys are here in court and Ms. Stipes is not
2 able to hear something, she is able to stop me or counsel and
3 we can get it corrected right in the moment. With the Zoom
4 setup, we are separated, in fact, we have a plexiglass between
5 us, it is not so easy. I appreciate your accommodation, and I
6 expect that everybody will comply with that request.

7 *MR. GILBERT:* Judge, would you repeat that email
8 address please?

9 *THE COURT:* Pauline_stipes@flds.uscourts.gov.

10 Now I would like to take up one last matter that we
11 were going to circle back to today. I think Mr. Agneshwar is
12 going to be able to answer that question and we wanted to get
13 to that this morning. As I understand, you also have another
14 matter, so I hope this doesn't pose any conflict for you, it is
15 just the one remaining question.

16 Good morning, Mr. Agneshwar, how are you?

17 *MR. AGNESHWAR:* I am good, your Honor. How are you?

18 *THE COURT:* Good. Thank you. Happy holidays, I see a
19 festive tree there in the background.

20 So, for the benefit of the record, my last question
21 yesterday when I was addressing the issue of innovator
22 liability and speaking to Mr. Cheffo, I had asked the following
23 question: According to paragraph 35 of the master personal
24 injury complaint, Defendant Patheon Manufacturing Services LLC,
25 referred to by the Plaintiffs within the category of Sanofi

1 Defendants, is a citizen of Massachusetts because its sole
2 member, Thermo Fisher Scientific, Inc. has its principal place
3 of business in Massachusetts. Thus, Massachusetts would have
4 the general personal jurisdiction over Defendant Patheon
5 Manufacturing Services. Massachusetts is one of two states
6 that recognizes Plaintiffs' theory of liability, albeit in a
7 limited way, Plaintiffs must allege Defendants acted
8 recklessly.

9 My question was, do you -- and whether that is
10 directed at you, Sanofi, Patheon Manufacturing LLC, but
11 ultimately the question is, does Patheon Manufacturing Services
12 LLC dispute that it is a citizen of Massachusetts?

13 MR. AGNESHWAR: Yes, your Honor, so I am Anand
14 Agneshwar, and I represent Sanofi. The jurisdictional
15 allegation about Patheon's home are correct, about its
16 principal place of business and state of incorporation. What
17 is not correct about the complaint is any suggestion that
18 Patheon is part of Sanofi.

19 Sanofi and Patheon are separate companies. Sanofi is
20 incorporated in states other than Massachusetts, and Sanofi is
21 the brand manufacturer that joined in the innovator liability
22 motion. Patheon manufactured some product for Sanofi, an arm's
23 length business relationship, but it is just not part of the
24 Sanofi entities.

25 The real problem with these allegations, it is not

1 correct to allege that Patheon is part of the Sanofi family.

2 *THE COURT:* So, Sanofi is disputing that Patheon is
3 part of the Sanofi affiliates, but you are representing that
4 Patheon is a citizen of Massachusetts.

5 *MR. AGNESHWAR:* That is correct, but I think it is
6 irrelevant to this particular motion because innovator
7 liability, as the Court well knows, is a theory that is
8 directed at the NDA holders of the product, the brand
9 manufacturers. Patheon was never a brand manufacturer or an
10 NDA holder of the product. It's not an innovator. So, the
11 motion doesn't apply to Patheon at all, so its residence
12 doesn't matter to the scope of this motion.

13 *THE COURT:* Okay. Okay, all right. Thank you.

14 That takes care of that followup question, I
15 appreciate it. Thank you for making yourself available this
16 morning.

17 *MR. AGNESHWAR:* Absolutely, your Honor. Thank you.

18 *THE COURT:* Take care.

19 Now we are going to turn to the motions for today. I
20 have received the revised schedule that the parties have agreed
21 to in terms of your allotment of time, so thank you for
22 agreeing. I always like it when parties can work things out
23 together, it is important to me, it is important to the
24 litigation, and hopefully you value the importance of it as
25 well.

1 The first motion that the Court is going to hear
2 argument on this morning is Docket Entry 1582 it is styled The
3 Generic Manufacturers and Repackagers Rule 12 Motion to Dismiss
4 on the Grounds of Preemption and Incorporated Memorandum of
5 Law.

6 And I see that Defendants have been allotted 23
7 minutes and the Plaintiffs have been allotted 20 minutes.

8 So, if I could have the Defendants turn -- counsel for
9 the Defendants turn your audio and video on and introduce
10 yourselves for the record. Then let me know if you want to
11 divide your time up; and if so, how, and whether the Court
12 giving you any warnings is of any help to you.

13 MR. BARNES: Good morning, your Honor, this is Rick
14 Barnes, I am appearing on behalf of the generic manufacturers.
15 I will be taking about 18 to 19 minutes. My associate, Mr.
16 Gugerty, will be handling the arguments pertaining to loss and
17 the repackager preemption argument, and Mr. Yoo will take the
18 lead on responding to your Honor's questions, and if there is
19 any time for rebuttal, he will handle that. I anticipate there
20 will be limited time for rebuttal.

21 THE COURT: Is that Mr. Gugerty in the room with you?

22 MR. BARNES: Yes, your Honor.

23 THE COURT: Is Mr. Yoo just going to come on for the
24 questions?

25 MR. BARNES: Yes, your Honor.

1 *THE COURT:* So, how did you want to divide your 23
2 minutes in terms of -- I might have missed that -- your opening
3 versus rebuttal?

4 *MR. BARNES:* I think I am going to take about 18
5 minutes and Mr. Gugerty will take the rest. If we have any
6 time left, it will be two minutes for Mr. Yoo. I do not expect
7 there will be any time left over, so let's not plan on any
8 rebuttal. It will probably be spent in the arguments. Mr.
9 Gugerty will probably take about four to five minutes on the
10 remaining arguments. I am handling implied preemption of state
11 law claims.

12 *THE COURT:* All right. Did you need any warning or do
13 you have that under control?

14 *MR. BARNES:* I've got it under control, your Honor.

15 *THE COURT:* All right. Take it away.

16 *MR. BARNES:* Good morning, may it please the Court.

17 The generic manufacturers' Motion to Dismiss on
18 preemption is based on the two landmark Supreme Court decisions
19 that Your Honor is very familiar with, *PLIVA* versus *Mensing* and
20 *Mutual Pharmaceutical v Bartlett*. Your Honor, as we set forth
21 in our briefing, the Supreme Court established a very
22 straightforward analysis for implied preemption as it relates
23 to generic drugs and generic manufacturers.

24 The analysis goes like this, it's a three-step
25 inquiry. First is, the Court has to examine the requirements

1 that exist under Federal law as to the generic manufacturers,
2 so what does Federal law require.

3 Second, the Court asks what the generic manufacturer
4 did do to avoid liability under the Plaintiffs' state law
5 claims.

6 And third, if Federal law prohibits a generic
7 manufacturer from independently taking the action needed to
8 avoid State Court liability, then the claim is found to be
9 preempted.

10 Under Federal law, the duties for generics are very
11 clear, they are set forth in the briefing, and yesterday
12 several times counsel referred to the duty of sameness and
13 that.

14 So, I won't go through the duty of sameness, your
15 Honor is well acquainted with it, but, essentially, it requires
16 the generic manufacturers to follow precisely the brand
17 manufacturers' labeling and to match in equivalence the design
18 of the molecule, in this case Ranitidine. So there is
19 no deviation, the duty of sameness requires a faithful
20 following of the brand label and the molecule.

21 I think it is conceded that the accuracy and adequacy
22 of the label for Ranitidine is the sole responsibility of the
23 brand manufacturers. The generic's duty is simply to follow
24 the brand. Yesterday, I think Plaintiffs conceded during
25 argument that the brands were the only ones who could change

1 the label and they are obviously correct in this.

2 So, in *Mensing* and *Bartlett* the Supreme Court held
3 that any Supreme -- I am sorry, any State Court law claim that
4 required a generic drug manufacturer to change the warning
5 labeling or the formulation of a drug conflicts with the duty
6 of sameness and is impliedly preempted. This is called
7 impossibility preemption.

8 The *Bartlett* Court, when it addressed this issue,
9 added an additional holding is that the Defendants cannot
10 comply with any State law duty and the Federal law duty by
11 simply not selling, or ceasing to act, or never selling the
12 medicine at all.

13 So, *Mensing* was decided nine years ago and *Bartlett*
14 was decided seven years ago, and in the intervening time, your
15 Honor, there have been at least 125 Federal District Court
16 decisions that have dismissed claims against generic drug
17 manufacturers on implied preemption grounds. At last count,
18 there have been 25 Federal Circuit Court decisions that have
19 affirmed such dismissals.

20 I think it is fair to say, when you spend the time
21 reading the decisions, it is fair to say that the Courts
22 apply *Mensing* and *Bartlett* broadly to give effect to the
23 supremacy clause.

24 What they do is they perform a functional analysis,
25 really, they look at the complaint and they say, well, at their

1 core what are they alleging? And usually these claims really
2 fall within adding new warnings, changing a drug's design, and
3 manufacturers never should have participated in manufacturing
4 and selling the product.

5 A good example of how the Federal Courts look at that
6 is the Eleventh Circuit's decision in Guarino versus Wyeth and
7 the quote goes something like this, no matter the garden in
8 which the Plaintiffs present the causes of action for warnings,
9 they all are barred and cannot escape Mensing's grasp.

10 I think the Courts have basically seen the three-step
11 analysis and have applied them uniformly to find preemption in
12 favor of the Federal law of supremacy.

13 All three complaints here -- I want to go back first
14 to the principles, if I might, your Honor. We are here today
15 because the allegation is that every single Ranitidine product,
16 every dose, every drop of syrup, every tablet, every capsule is
17 defective because of chemistry, it is alleged to have an
18 inherently unstable design, molecule. The molecule is
19 foreordained to degrade and it does so, according to the
20 complaint, under normal anticipated circumstances.

21 This is the core allegation that set off this MDL, is
22 the very nature of the Ranitidine molecule itself.

23 With this core allegation as the factual predicate the
24 Plaintiffs' claims are basically one of three theories. Given
25 the inherent propensity of this molecule to degrade the generic

1 Defendants should somehow warned of it, that is number one.

2 Number two, they should have changed the design of the
3 drug and should have changed the manufacturing process to
4 prevent the inherent flaw from occurring.

5 And three, it is so dangerous that generics should
6 have stopped selling Ranitidine or never have sold it in the
7 first place.

8 All of the causes of action, your Honor, basically
9 fall within that framework.

10 So, as we go through this, just remember this -- the
11 fundamental feature of this case is the uniformity in the
12 design being the issue, there is no exemption, there is no safe
13 harbor, no period, no formulation that they claim is reasonably
14 safe.

15 With that, let me move on to another subject, and that
16 is, so, given the clear holdings and the uniform application in
17 Federal Courts of Mensing and Bartlett to dismiss product
18 liability claims against the generics, how can the Plaintiffs
19 proceed here?

20 If you go through the complaint, all 15 causes of
21 action, and you go to the case law, every one of them have been
22 found to be preempted and dismissed as a matter of law. What
23 they do is, they say, well, there are alternate theories of
24 liability that are distinct from the holdings in Mensing and
25 Bartlett, and that these theories actually are so different

1 that they are immune from the implied preemption case law.

2 The Plaintiffs' briefs are well presented, but to read
3 their briefs one gets the impression that these theories have
4 somehow escaped the gaze of Federal Courts and the Plaintiffs
5 Bar in this country over the past nine years, and actually all
6 of these theories have been considered and uniformly rejected.

7 So, while the arguments are presented with a level of
8 certitude, that doesn't exist in the case law at all.

9 Starting with Mensing and continuing to the present,
10 Courts time and time again have declined these theories, they
11 are always found to be preempted. In reality, Courts recognize
12 that these are usually a product of pleadings that are created
13 to find a loophole, to find some end run around the Mensing and
14 Bartlett decisions.

15 Simple fact, your Honor, Plaintiffs have failed to
16 produce a single case in which a Court, faced with a Motion to
17 Dismiss a generic drug case, has accepted any of the
18 Plaintiffs' alternate theories sufficient to overcome implied
19 preemption under Mensing, Bartlett, and the substantial Federal
20 Court jurisprudence on implied preemption.

21 Your Honor, I think it is fair to say that the
22 Plaintiffs are asking this Court to become the first one
23 anywhere in the country to accept this approach and find a
24 loophole, find an alternate theory to let their state law
25 claims survive.

1 I would like to spend my time walking through these
2 alternate theories, and there are, to our reading, four basic
3 approaches that the Plaintiffs are urging the Court to accept.

4 The first one is a duty to warn the FDA. There is a
5 duty to warn third parties, in this case the Food and Drug
6 Administration.

7 Reframing their failure to warn case in this manner
8 basically is their way of saying that, well, we have -- we have
9 our way through, but Mensing actually dealt with this issue and
10 explicitly rejected an alternate theory of failure to warn the
11 FDA as a premise of a state law cause of action, and Mensing
12 does this at 564 U.S. at 620 and 621.

13 This principle was also rejected in the Allbright case
14 from the Southern District of Florida, rejected the same
15 failure to warn the FDA theory, and that's Allbright versus
16 Teva, Southern District of Florida, 2017.

17 The authorities that Plaintiffs provide the Court in
18 support of this are from the express preemption jurisprudence
19 in the medical device context and the context of parallel
20 claims, and that is far afield from the supremacy clause
21 jurisprudence and implied preemption.

22 Your Honor, express preemption is express because it
23 is expressed in a Federal Statute, it is a creature of statute,
24 and Courts construe the intention of Congress in the words of a
25 statute.

1 The words at issue here, the medical device
2 amendments, is that -- the express preemption clause is 21
3 U.S.C. Section 360(k). It provides that only state laws that
4 are different from or in addition to Federal law are preempted.

5 So, Courts in the medical device field looking at this
6 specific statutory language have held that state laws that are
7 merely parallel, which is construed as being identical to
8 Federal law as to medical devices are not expressly preempted.
9 The word "parallel" in this context means parallel between the
10 state law and the Federal law. So, it arises from statutes and
11 it arises from the express intention of Congress.

12 This concept of express preemption and parallel claims
13 and parallel lawsuits have no application in implied
14 preemption. It is foreign to the supremacy clause where that
15 language does not appear anywhere. The supremacy clause deals
16 with the superiority of Federal law as it relates to
17 conflicting state law, and in that situation state law gives
18 way.

19 So, all of these cases in their brief that they insert
20 into the implied preemption arguments simply have no --

21 *THE COURT:* Wait, Mr. Barnes, just hold on one moment.

22 If there is somebody here, a participant who has not
23 muted your audio, please do so. We hear noise in the
24 background. Thank you.

25 *MR. BARNES:* Thank you, your Honor.

1 There are several Courts that have held that the
2 concept of express preemption, parallel claims has no place in
3 the generic drug preemption jurisprudence. We have cited those
4 cases in our briefing, and the contrary view is all based upon
5 express preemption in medical device cases.

6 I want to point the Court to what the Court in Mensing
7 said towards the end of the opinion, and the Court recognizes
8 that different statutes and different repertory schemes may
9 result in very different outcomes with respect to Federal
10 preemption. The Mensing opinion points out as to implied
11 preemption, Federal Courts should not distort the supremacy
12 clause to create similar preemptive outcomes across dissimilar
13 repertory schemes.

14 Nothing could be more different than the medical
15 device amendments, which there are no such thing as a generic
16 medical device, so it is a very distinct repertory program.

17 The bottom line, your Honor, is that express
18 preemption cases upon which the Plaintiffs base their
19 efforts to avoid preemption should not be viewed as overriding
20 the very clear holdings of Mensing, Bartlett, and the dozens
21 and dozens and dozens of Federal Court cases that have found
22 implied preemption in favor of the generic manufacturers.

23 So that is the first effort, and then in a related
24 concept, there is an argument about parallel misbranded. It
25 fails for the same reason as a parallel claim, it is derived

1 from medical devices -- express preemption case law, maybe even
2 a case or two thrown in that is herbicides, not a generic drug,
3 it is a different reparatory scheme, so the parallel
4 misbranding claim fares no better.

5 Ms. Eisenstein will be handling this argument as it
6 relates and was primarily briefed in the OTC express preemption
7 motion which the brands files that the generics join, so I
8 remind your Honor that we are joining in her argument on
9 express preemption there, and she will spend a little more time
10 on this parallel misbranding issue.

11 So, in the interest of time, I am going to focus on a
12 few brief points as it relates to the generics.

13 Again, it is a creature of express preemption.
14 Second, Plaintiffs' parallel misbranding theory has never been
15 adopted by any Court with respect to a generic manufacturer.
16 There have been three Courts that have declined to adopt the
17 parallel misbranding approach.

18 First, the Supreme Court in Bartlett, it did not
19 accept the premise of a parallel misbranding cause of action
20 against a generic manufacturer, the Sixth Circuit in Darvocet,
21 and then the Southern District of Illinois in Yasmin & Yaz, and
22 that was an MDL.

23 The fundamental reason that all Courts that have
24 considered this issue have rejected it is that it creates such
25 a broad loophole into the bright line generic drug preemption

1 jurisprudence.

2 I want to point out in Darvocet that the Court
3 basically looked at it this way, and it arises from the
4 Bartlett decision, but they said if this cause of action would
5 be viable against a generic drug manufacturer, it would only
6 apply in a pure design defect context. A pure design defect
7 context does not implicate the warnings.

8 The Plaintiffs have stated very clearly that their
9 design defect theory is based solely upon inadequate label.
10 That runs squarely into Mensing and should be rejected on that
11 score, and I think under Bartlett and Darvocet, it would not
12 survive preemptive challenge.

13 Our position is, if you accept that point of view,
14 Mensing is a nullity and the supremacy clause becomes really
15 meaningless with respect preemption to generics. It is just
16 too simple a formulaic allegation that obliterates the entire
17 line of cases.

18 Plaintiffs' testing claims are preempted. I just want
19 to remind the Court that this has been addressed in two cases,
20 one is Drager versus PLIVA, Fourth Circuit, and in Morris
21 versus PLIVA in the Fifth Circuit, and in this Court also in
22 Allbright in the Southern District of Florida.

23 The fundamental premise here is that because the
24 ultimate duty to the consumer is that the -- it is not to
25 conduct a specific test, but it is not to have a negligent sale

1 or sell an unsafe product, and the way that manufacturers do
2 that is either warn of the latent defects discovered by the
3 test, redesign the product, redesign the drug, or simply stop
4 selling it.

5 All of these, again, in this functional analysis, the
6 Courts look at it and say this law requires actions that are
7 preempted, and they reject this sort of approach. It also
8 applies to failure to inspect and other such theories.

9 They say, well, we could have had a shorter expiration
10 date. I remind the Court that this case is about every drop,
11 every pill, every capsule is prone, according to the
12 Plaintiffs, to degrade and do so promptly. That is why we are
13 here. They don't allege that from a two-year expiration date
14 to a one-year expiration date creates a safe product. It is a
15 product line defect, it starts on manufacture and continues.

16 So, I would say that even if you assume that a shorter
17 expiration date, they make this point, would result in less
18 NDMA, they don't say that makes the product safer, and that
19 people aren't prone to cancer.

20 To the contrary, every pill counts according to their
21 cause of action and their arguments yesterday. Time and time
22 again they made the point that it is a dangerous product and no
23 exceptions. Well, if that is the case, that expiration date
24 would not alleviate State Court liability for the generics.
25 There is no reason not to reject this claim.

1 Manufacturing and storage, briefly, storage is
2 preempted under the duty of sameness. I'll just point out,
3 your Honor, that a syrup generic and a syrup brand have the
4 same storage conditions by the duty of sameness and comparable
5 formulations would have to follow the brand.

6 Secondly, on the manufacturing defect, it is really a
7 design defect. You can make the product perfectly and they are
8 claiming it will degrade into NDMA.

9 I'd also point out that the relevant change here, if
10 they were going to change the manufacturing, would affect the
11 purity profile, the quality of the drug, and under 21 CFR
12 314.70(a)(2), that would be a major change that requires FDA
13 pre-approval and thus, would be preempted under Mensing and
14 Bartlett.

15 Your Honor, I think that is the summary of our
16 argument and we will be happy to take questions later. Mr.
17 Gugerty will now proceed on Magnuson-Moss. Thank you, your
18 Honor.

19 *THE COURT:* Thank you. It is about 20 minutes and 26
20 seconds.

21 *MR. GUGERTY:* Thank you, your Honor. All right.

22 Your Honor, for the Magnuson-Moss claim there are two
23 points for the dismissal of that claim. Number one, it is
24 undisputed that the Magnuson-Moss Act, which is a Federal
25 Statute, requires a predicate state law claim for breach of

1 warranty in order to move forward.

2 As Mr. Barnes explained, all of Plaintiffs' state law
3 warranty claims are preempted and must be dismissed as to the
4 generic manufacturers, and as I'll go through in just a moment,
5 the same is true for the state law warranty claims as to the
6 repackagers. They, too, are preempted and must be dismissed
7 under Mensing.

8 The Plaintiffs lack that state law anchor claim for
9 breach of warranty that they would need for the Magnuson-Moss
10 Act and therefore the Magnuson-Moss Act claim fails and must be
11 dismissed.

12 The second point for Magnuson-Moss is that Section
13 2311(d) of that statute provides that it is inapplicable to any
14 written warranty the making or content of which is otherwise
15 governed by Federal law. That is true, of course, for generic
16 drugs, their labeling is governed under the Federal duty of
17 sameness.

18 The majority of Courts who have considered the issue
19 have held that Section 2311(d) requires the dismissal of
20 Magnuson-Moss Act claims and claims for generics or other FDA
21 approved drugs. Those decisions have primarily been at the
22 Rule 12 stage. The Plaintiffs only counter to that, your
23 Honor, they argue that their Magnuson-Moss implied warranty
24 claim should somehow escape preemption, and that claim fails.

25 The only case they cite is a homeopathic drug case,

1 which is distinguishable. The FDA doesn't review labeling for
2 homeopathic drugs, so it doesn't have any bearing on generics
3 where the FDA does.

4 The Plaintiffs are very clear in their complaints that
5 both their implied and express warranty claims are based
6 entirely on the labeling. That is paragraph 425 of the
7 personal injury complaint, 342 of the TTP complaint, and
8 similar allegations in the class.

9 Lastly, your Honor, as to the repackager complaints --
10 excuse me, the state law claims against repackagers, they, too,
11 are preempted and must be dismissed under a straightforward
12 extension of Mensing and Bartlett.

13 The repackagers did not hold the FDA approved drug
14 applications for the products they sold. That is undisputed.
15 Because of that, under Federal law, only the applicants, the
16 holders of the NDAs or the ANDAs, can make changes. The
17 repackagers could not under Federal law. So, Federal law
18 conflicts with the state law claims brought against the
19 repackagers. Under the principles of Mensing and Bartlett,
20 those claims fail and must be dismissed.

21 Numerous Courts have so held, including most recently
22 in the country this Court in the Smith v Teva decision from
23 February of this year, and that's 47 F.Supp.3d 1159. And the
24 Plaintiffs' only response to that is to cross reference their
25 opposition to the retailer and distributor groups motions, and

1 I know their counsel will address that, so I won't say anything
2 on that subject, your Honor. Thank you very much.

3 *THE COURT:* Okay, thank you very much.

4 Okay. If we could have Plaintiff come on the screen,
5 counsel for the Plaintiffs, for a 20-minute presentation, and
6 state your appearance for the record.

7 *MR. KELLER:* Good morning, your Honor, Ashley Keller
8 for the Plaintiffs. Can you see me and hear me okay?

9 *THE COURT:* Yes, I can see you and hear you. You may
10 proceed.

11 *MR. KELLER:* Good morning, your Honor, may it please
12 the Court, Ashley Keller again for the Plaintiffs.

13 I would like to start with principles of preemption
14 law and then apply those principles to our misbranding theory,
15 failure to warn the FDA, and expiration dates, but because
16 misbranding is a theory that applies to all Defendants, I would
17 like to take a moment and set the stage for that discussion.

18 It is worth zooming out to see the big picture as
19 described in the master complaints. Zantac was first approved
20 by the FDA almost 40 years ago in 1983. Post approval, it
21 quickly became one of the best selling drugs of all time. In
22 fact, the industry defines a blockbuster franchise as a drug
23 that achieves a billion dollars in annual sales. Zantac was
24 the first drug ever to reach that milestone.

25 When generics entered the market two expected things

1 happened, the price went down and total consumption went up.
2 All told, millions upon millions of Americans have taken
3 Ranitidine on a daily basis for years or even decades. To say
4 the drug was ubiquitous in the United States is an
5 understatement. Yet, as we all know, Ranitidine is not
6 lawfully sold anywhere in the United States today.

7 Why is that? As alleged in the complaints, it is
8 not because Ranitidine is just as safe as bacon or smoked meat,
9 and I promise, your Honor, it is not because the Defendants no
10 longer care about making a profit. No. The drug is off the
11 market everywhere because of new and scientifically significant
12 information that was not in front of the FDA.

13 The FDA didn't know in 1983 what we know today, that
14 Ranitidine breaks down in significant quantities over time into
15 NDMA, which is a deadly compound that causes cancer. That is
16 why it is off the shelves.

17 This situation is the textbook case the FDA had in
18 mind when it embraced our theory of liability seven years ago.
19 Though the agency couldn't have known about this MDL in 2013,
20 when it submitted its amicus brief in Bartlett, this MDL
21 captures the precise fact pattern where states' stop selling
22 duties and Federal law aligned.

23 Unlike in Bartlett, we are not asking the Court to let
24 us argue to a jury that the FDA made a mistake when it reviewed
25 the same scientific evidence in 1983. We are arguing that a

1 jury should agree with the agency, the devastating new
2 information the FDA never saw confirms that Ranitidine meets
3 the definition of a misbranded drug. If our misbranding theory
4 can't succeed, the FDA is wrong and no theory can.

5 If our misbranding theory can't succeed, then state
6 law will be barred from imposing civil liability, even where it
7 is clear as day that such liability promotes and furthers the
8 precise policies embodied in the national regulatory scheme set
9 up by Congress. That is not the law, as I hope I am about to
10 demonstrate to your Honor.

11 Let me return to the background principles of
12 preemption jurisprudence. Preemption is about conflict of law
13 and it flows from the Constitution. Federal law is the supreme
14 law of the land. Anything in the constitution or laws of any
15 state to the contrary notwithstanding, that's Article VI,
16 Clause 2.

17 There are several different categories of preemption,
18 as we just heard. There is express versus implied, and then
19 within the implied category there is objects and purposes
20 preemption, field preemption, and as primarily relevant here
21 today, implied impossibility preemption. As the Supreme Court
22 said just two terms ago in *Allbright*, implied impossibility is
23 a demanding defense. To win the Defendants must show that it
24 is impossible to simultaneously comply with state and Federal
25 law.

1 On the flip side, it follows that where state and
2 Federal law are parallel, where they are the same, it can't be
3 impossible to comply with both.

4 Courts begin the preemption analysis by comparing
5 state and Federal duties to see if they conflict. The Supreme
6 Court has said this multiple times in cases like Moore,
7 Bartlett, and Mensing.

8 There are three corollaries to this starting rule,
9 your Honor. First, state and Federal duties don't have to use
10 the same words to be in harmony, they just have to be
11 substantively consistent. "To survive preemption the state law
12 requirement need not be phrased in the identical language as
13 its corresponding Federal law requirement. Indeed, it would be
14 surprising if a common law requirement used the same
15 phraseology as Federal law." That is the Supreme Court in
16 Bates at 454.

17 The Defendants accuse us repeatedly of not styling our
18 cause of action misbranding, or not using the word misbranding
19 enough in the complaints, but that ignores the teaching of
20 Bates. It is not about matching words for preemption purposes,
21 it is about the substance of the state and Federal duties.

22 Second, your Honor, as the Eleventh Circuit observed
23 in Mink, state law claims can create multiple duties, and only
24 some of them might conflict with Federal law. Where that is
25 the case, preemption applies only to the extent of the

1 difference between state and Federal responsibilities. That is
2 once again Bates at 453.

3 So, to offer your Honor a highly stylized example,
4 suppose a state cause of action creates duties A, B, and C, and
5 Federal law makes it impossible to comply with duty C. A
6 Plaintiff can still plead and prove her case based on either
7 duty A, a breach of duty A, or a breach of duty B. There is
8 only preemption to the extent of the difference.

9 Finally, your Honor, to go back to where we began,
10 preemption is about comparing duties, not the other elements of
11 state torts. Though those additional elements such as
12 causation or injury must be pleaded or proved, "such additional
13 elements would make the state requirements narrower and provide
14 a strange reason for finding preemption of a state rule insofar
15 as it duplicates the Federal rule." That is the Supreme Court
16 at Moore, at 495.

17 Let's apply these principles to our misbranding
18 theory, your Honor, to demonstrate that they are not
19 preemptive. Once again we begin by comparing state and Federal
20 duties. Nobody disputes that state design defect law imposes
21 multiple duties, one of which is to not sell a defectively
22 designed product.

23 The Supreme Court accepted that formulation of design
24 defect duty in Bartlett under New Hampshire law and the law of
25 design defect is virtually the same everywhere. You must not

1 sell a defectively designed product. That is the state side of
2 the ledger.

3 Let's compare that to the Federal responsibilities
4 created under the FDCA. In order to do that we first have to
5 turn to the statute's definition of a misbranded drug. A drug
6 is misbranded if its label is false or misleading in any
7 particular. That's 21 U.S.C., Section 352(a)(1), or if it is
8 dangerous to health when used in the dose, manner, or frequency
9 stated on the labeling thereon. That's Section 352(j).

10 With that definition in mind, what are the duties
11 created by the Federal misbranding provision? This is
12 contained at Section 21 U.S.C., 331(a), (c) and (g). Quite
13 simply, you cannot manufacture, introduce, deliver, or receive
14 a misbranded drug in interstate commerce. In other words, the
15 Federal duty exactly matches the state responsibility, do not
16 sell a misbranded drug.

17 The Defendants offer several rebuttals, but none of
18 them are persuasive.

19 First, the Defendants say that they cannot as a matter
20 of law sell a misbranded drug so long as they affix the FDA
21 approved label. In other words, FDA approval in the past, back
22 in 1983, guarantees that a drug is not misbranded any time
23 after that.

24 That is false, your Honor. The Supreme Court rejected
25 that in Bartlett in Footnote 4 saying, "the misbranding statute

1 requires a manufacturer to pull even an FDA approved drug when
2 it is dangerous to health." The Code of the Federal Register
3 says the exact same thing, 21 CFR 314.170, all drugs, including
4 those the FDA approves, are subject to the adulteration and
5 misbranding provisions of the FDCA.

6 There is, quite simply, no shield to liability just
7 because a drug was approved 40 years ago.

8 Let's address the elephant in the room, your Honor,
9 which is the Supreme Court's decision in Bartlett. Every
10 category of Defendant accuses us of trying to make an end run
11 around the decision. You just heard the exact same thing from
12 my friend. I think it is important for us to not overstate or
13 understate what the Supreme Court said in Bartlett.

14 Footnote 4 is crystal clear that it is not deciding
15 the question that we pose today. The generic manufacturers say
16 that Footnote 4 is obscure and mere dicta, so the Court should
17 pay no attention to it.

18 With all due respect, your Honor, when the Supreme
19 Court of the United States announces the scope of its holding,
20 that is part of the holding, not dicta. When the Supreme Court
21 of the United States leaves a question open, it is inviting
22 lower Courts not to apply principles of vertical stare decisis.
23 It is saying that you get to decide this issue de novo based
24 on first principles of preemption jurisprudence.

25 It is not an end run around the Supreme Court's

1 decision to take up the invitation that they left open to us,
2 and our case is nothing like Bartlett. There the Plaintiffs
3 were asking the jury to second-guess the FDA science
4 determinations by presenting the same evidence that the FDA
5 considered and rejected as to the safety profile of Sulindac.

6 Here, we are arguing that new and meaningful science
7 came to light since in 1983 that caused the FDA to agree with
8 us. They told every Defendant, stop selling Ranitidine, it is
9 dangerous. What possible policy is served by not allowing
10 liability here?

11 Our duties under state law are exactly parallel to the
12 duties under the misbranding statute. There cannot be
13 preemption when there are parallel claims like this, which
14 raises an important objection, your Honor, that the Defendants
15 made, and you heard it from my friend a few moments ago.

16 They say we have committed a category error because we
17 are using the language of parallel claims and that is an
18 express preemption concept and we borrowed that from a bunch of
19 Medical Device Act cases that we say are on point that we cited
20 to the Court, but pay no attention to that, they say, because
21 ours is an implied impossibility preemption theory, so those
22 express preemption cases are inapposite.

23 Your Honor, we agree that the parallel claims concept
24 is something we borrowed from the Medical Device Act, but the
25 Defendants are profoundly mistaken about the ramifications of

1 that for their theory and makes our theory ironclad and
2 disposes of their theory.

3 To see that, let's recall the language of the express
4 preemption clause from the Medical Device Act, which is
5 actually quite broad and it mirrors the language of the OTC
6 regulation at issue here, 379(r). State duties are preempted
7 if they are in addition to, different from, or not identical
8 with Federal law. The only duties that can survive preemption
9 are the ones that are exactly the same as the Federal duties.

10 So, I have a simple question for my friends. How can
11 Federal law make it impossible to do what state law requires
12 when both state and Federal law require the exact same thing?
13 If state law says do X, and Federal law says do X, how can it
14 be impossible to do X?

15 I pose my question as a challenge. I challenge any
16 Defendant to stand before the Court today and offer a single
17 concrete example from a real case, or one that they come up
18 with hypothetically, where state and Federal duties are
19 identical, there's no daylight between them, and yet it is
20 impossible to do both.

21 They cannot meet this challenge, your Honor. It is a
22 logical and legal impossibility to show impossibility when you
23 survive an express preemption clause as broad as the one under
24 the Medical Device Act, which is a good segue, your Honor, to
25 the failure to warn the FDA claims because they make the same

1 objection with respect to that theory.

2 Once again we begin by comparing state and Federal
3 duties.

4 Under the state law of states such as California,
5 which recognize the theory in Coleman versus Medtronic, as well
6 as other states like New York, or Pennsylvania, or Mississippi,
7 the common law duty to warn includes a duty to update third
8 party agencies such as the FDA when the agency is the most
9 efficient means of getting the warning to the ultimate
10 consumer. No one disputes that state law embraces that form of
11 duty under the law of some states.

12 What is the Federal set of duties? The FDA says they
13 are the exact same ones. The FDA's position, backed up again
14 by the Code of the Federal Register, states that generic
15 manufacturers, just like their branded counterparts, have an
16 obligation, a duty under Federal law to keep the agency abreast
17 of new and emerging science that would call into question the
18 safety and efficacy profile of their drugs.

19 So, once again, because the state and Federal duties
20 are parallel, it can't be impossible to comply with both, and
21 an unbroken line of cases, starting with the Ninth Circuit's
22 unanimous decision en banc in Stengel, followed by Basch and
23 Striker and Mink, reaffirm this point.

24 The first objection the Defendants make is the one
25 that we already went over, that we are talking about parallel

1 claims, but that can't bear on their impossibility analysis.
2 As I have already demonstrated, that is a logical fallacy. It
3 proves that our claims aren't impossible to simultaneously
4 comply with.

5 The next objection that the generic manufacturers made
6 is, they said we played a game of hide the ball with respect to
7 Stengel, your Honor, because the Arizona Supreme Court
8 subsequently said Arizona does not recognize the California
9 common law duty to update third party agencies like the FDA.

10 With all due respect, we didn't cite the Ninth
11 Circuit's decision for the Erie guess that it made. We
12 agree it made an erroneous Erie guess and Arizona is entitled
13 to not embrace the same form of duty as California law.

14 We didn't cite Arizona as an example of a state that
15 embraces the California style duty to warn. We cited Stengel
16 for the proposition that there is no preemption under the
17 supremacy clause under these circumstances and it remains
18 perfectly good law on that Federal question.

19 The next objection that the Defendants lodge is
20 Buckman preemption, but Buckman doesn't apply. The penultimate
21 paragraph oh Chief Justice Rehnquist's opinion, and for the
22 Court is the relevant one, it says you can't try to enforce
23 state duties that rely solely on Federal law, but our theory
24 under California and other state's law doesn't rest solely,
25 primarily, or at all on Federal law.

1 If the FDCA were repealed tomorrow, if the
2 FDA tomorrow repealed the regulation requiring generic
3 manufacturers to keep the agency abreast of emerging science,
4 state law under the common law of California would still impose
5 the exact same duties. So, our duties don't rest on trying to
6 enforce the Federal statutory scheme.

7 Finally, your Honor, they say once again that Mensing
8 squarely foreclosed our theory, but it doesn't. In Mensing the
9 Court said, quote, "the only action the manufacturers could
10 take asking for the FDA's help is not a matter of state law
11 concern." That's at 604. And at 619, the Plaintiffs expressly
12 denied "that their state tort claims are based on the
13 manufacturer's alleged failure to ask the FDA for assistance in
14 changing the label."

15 Our claims do make those issues matters of state law
16 concern because that is what the law of California says. Like
17 it or not, the generic manufacturers have to accept the duties
18 as announced by the state courts under the state's common law.

19 Let's transition in conclusion, your Honor, to the
20 expiration date theory because I think once again Mr. Barnes
21 has changed his position from the opposition that he initially
22 expressed through the reply brief. So, we begin once more by
23 comparing state and Federal duties.

24 The state failure to warn clearly encompasses a duty
25 to have an accurate expiration date. Federal law says the

1 exact same thing for both branded and generic manufacturers.
2 In their opening brief the Defendants attempted to say that we
3 conceded that the duty of sameness said they couldn't have a
4 different expiration date, or they tried to say that maybe the
5 initial expiration day when they submitted their ANDA could be
6 different from the reference listed drug, but they couldn't
7 make any changes after the fact.

8 All of that is incorrect under the regulatory regime,
9 as we demonstrated in our opposition. Let's start with the
10 duty of sameness, the so-called duty of sameness. That is 21
11 CFR 314.94(a)(8) little 4.

12 It does say that the branded label has to match the
13 reference listed drug in most respects, but there is an express
14 exception for differences in expiration dates. There is no
15 ambiguity about that. The expiration dating provision
16 expressly says that the original date might need to be changed
17 post approval through a supplement. That is 211.166(b).

18 ANDA holders are subject to the same provisions as NDA
19 holders to make changes through supplements. That is
20 314.97(a).

21 The rules for supplementing an application for an ANDA
22 holder are the exact same ones that apply for the original
23 ANDA. That is 21 CFR 314.71.

24 So, there is no duty of sameness with an exception for
25 expiration dates that applies only initially as opposed to for

1 the supplemental process.

2 As Mr. Barnes already covered, 314.70 is the provision
3 that governs ANDA holders for making changes, and the FDA has
4 already said through interpretive guidance that making a change
5 to shorten an expiration date is a moderate change under
6 subsection C. That is the exact same CBE provision that was at
7 issue in Wyeth versus Levine.

8 So, the generic manufacturers have shortened their
9 expiration date without the FDA's special permission or
10 assistance, there is, therefore, no preemption.

11 They run from this argument in their reply brief, and
12 you heard Mr. Barnes did the same thing in his presentation
13 saying, maybe as a matter of law we could have shortened our
14 expiration dates, so pay no attention to our opening
15 submission. But then they just ignore the 12(b)(6) standard
16 and say, even if we could have legally done that, the
17 Plaintiffs' theory doesn't allow it because we allege that
18 Ranitidine is always dangerous.

19 Your Honor, we also allege that the expiration dates
20 are inaccurate and could have been shortened, and this again
21 forgets the teaching of Bates. Just because they can't do
22 everything required by state law, such as changing the
23 formulation of the molecule, doesn't mean that they are
24 absolved from doing some things that state law allows.

25 They could have changed their expiration date

1 consistent with both sovereigns' set of duties. They were
2 required to do so. And the fact that they couldn't also change
3 the molecule, because that would have been a major change that
4 would have fueled the finding of preemption, doesn't shield
5 them from liability.

6 Thank you, your Honor. I am happy to come back on to
7 field any questions at the appropriate time.

8 *THE COURT:* Thank you. You can actually stay on and I
9 will invite the Defense to come on as well. Turn your audio
10 and video on so we make sure we have everybody. And again,
11 when you speak, if you'd state your name for the record. And I
12 will leave it up to you, at least as among the Defendants, who
13 wants to answer the question, because I see there are several
14 counsel for the Defense.

15 So, for the Defense, the preemption motion states that
16 it is a Rule 12 motion. Is it correct that the motion is a
17 Rule 12(b)(6) motion based on an affirmative defense?

18 *MR. YOO:* Correct, your Honor, it is a 12(b)(6) motion
19 based on Plaintiffs' failure to state a claim.

20 *THE COURT:* For the record, that is Mr. Yoo.

21 *MR. YOO:* Thank you, your Honor.

22 *THE COURT:* Again, for the Defense, but Plaintiffs can
23 listen, it will be the same question.

24 Does Plaintiff agree that impossibility preemption
25 means that a state law imposes a duty or obligation to do

1 something, but Federal law prevents you from doing it? For the
2 Defense.

3 MR. YOO: I'm sorry, your Honor. I apologize, could
4 you repeat that question, please?

5 THE COURT: Sure. Do you agree that impossibility
6 preemption means that a state law imposes a duty or obligation
7 to do something, but Federal law prevents you from doing it?

8 MR. YOO: This is Thomas Yoo for the Defense. Yes,
9 your Honor, that is part of the implied preemption
10 impossibility analysis.

11 THE COURT: And from the Plaintiff.

12 MR. KELLER: We agree, your Honor. We don't think it
13 is part of the implied impossibility analysis, that is the
14 analysis.

15 THE COURT: That was Mr. Keller. So, just again
16 remember to state your name before you speak. Would you say
17 that again, please.

18 MR. KELLER: Of course. I'm sorry, Ashley Keller for
19 the Plaintiffs. Yes, we agree that that is the entirety of the
20 analysis, is it impossible to comply with state and Federal
21 duties at the same time.

22 THE COURT: This question is both for Plaintiffs and
23 defense as well. You both have cited to an April 2004 FDA
24 manual titled "Guidance for Industry: Changes to an Approved
25 NDA or ANDA" in the briefing for the Motion to Dismiss on

1 preemption grounds.

2 Are the parties, then, in agreement that the Court can
3 take judicial notice of this FDA manual and consider it at the
4 Motion to Dismiss stage? From the Defendants.

5 MR. YOO: Thomas Yoo for the Defendants. Yes, your
6 Honor.

7 THE COURT: For the Plaintiffs.

8 MR. KELLER: Ashley Keller for the Plaintiffs. Yes,
9 your Honor.

10 THE COURT: This is a question for Plaintiffs.

11 Can you identify for the Court any generic drug that
12 has ever had a different expiration date period than the brand
13 name version?

14 MR. KELLER: Yes, your Honor, Ranitidine.

15 THE COURT: Can you identify any generic drug that has
16 ever been found by the FDA, a court, or a jury to require a
17 different expiration date period than the brand name version?

18 MR. KELLER: Your Honor, the FDA's regulations impose
19 this duty on the manufacturers to choose the expiration date.
20 So, I would argue that, under FDA regulations, it is the
21 FDA insisting that the ANDA holder for Ranitidine have a
22 shorter expiration date, but I can't cite to you an express
23 finding by the agency itself that Ranitidine, or any other
24 drug, should have had a shorter expiration date. I don't have
25 that at my fingertips.

1 Ashley Keller again for the Plaintiffs. I am sorry,
2 Ms. Stipes.

3 *THE COURT:* Again this is for the Plaintiffs.

4 Could a state, for example, impose a law that all
5 drugs sold within the state must have a three-month expiration
6 date period, for example? Or that all generic drugs must have
7 a three-month expiration date period? Would that be preempted,
8 and why or why not? That is for the Plaintiff.

9 *MR. KELLER:* Your Honor, that would potentially be
10 preempted to the extent that three months is not an accurate
11 expiration date under the FDA regulations.

12 So, the FDA insists that an expiration date be set to
13 ensure the qualities of identity, strength, quality, and purity
14 of the drug. So, if a three-month period would not be accurate
15 under that standard, there would be preemption because it would
16 be impossible for a manufacturer to comply with that while also
17 complying with the Federal regime insisting on accuracy in the
18 date.

19 *THE COURT:* And the same would go if a state imposed
20 an even shorter expiration date such as one week? Would it be
21 the same answer?

22 *MR. KELLER:* I believe that it would be the same
23 answer to the extent that one week was inconsistent with the
24 date that should be set based on the Federal stability testing
25 that the manufacturer is supposed to undertake.

1 So, the state duty would be consistent with Federal
2 law if it said, put an accurate expiration date on your
3 product. If it is requiring it to be shorter, even if that is
4 not accurate, I think there could be impossibility preemption
5 there. That would be a tougher case, but I think there could
6 be impossibility preemption in that instance.

7 *THE COURT:* For the Plaintiffs again, if a drug
8 manufacturer learned that its drug, if it sits on store shelves
9 for too long, causes cancer, would the law of any state be
10 satisfied with simply shortening the expiration date on the
11 packaging?

12 A followup question would be: Why wouldn't a state
13 also require better warnings, a redesigned drug, and/or removal
14 of the drug from the market? Those are the totality of
15 questions on that topic.

16 *MR. KELLER:* Ashley Keller for the Plaintiffs. That
17 is a great question and it illustrates the point I was making
18 at the end of my prepared remarks.

19 No, the law of no state would be fully satisfied by
20 just shortening the expiration dates, however, the law would be
21 partially satisfied by complying with those state duties. As
22 the teaching of *Bates* reminds us, preemption only applies to
23 the extent of a difference between state and Federal law.

24 So, if state duties are A, B, and C, and A is the most
25 maximalist one, it requires the manufacturer to do the most

1 things, but that is impossible under Federal law, they are not
2 absolved from responsibility for performing duties B and C.

3 So, to put this back into the context of Ranitidine,
4 we agree that no manufacturer post approval of their drug
5 could, without the FDA's special permission or assistance, to
6 use the language of Mensing and Bartlett, redesign the molecule
7 or change the formulation. Those are major changes that would
8 require FDA approval, but they could have changed the
9 expiration date. The brand manufacturers could have added a
10 cancer warning.

11 Those lesser responsibilities under state law still
12 have full force and effect and are not in conflict with Federal
13 law.

14 MR. YOO: Your Honor, may I be heard on this issue?

15 THE COURT: Yes.

16 MR. YOO: With regard to the Plaintiffs' arguments
17 concerning expiration dates, we have to start by recognizing
18 that the Plaintiffs have made it clear by their allegations
19 that there is no safe effective expiration date.

20 Despite their efforts to use expiration date as a hook
21 in their opposition to our Motion to Dismiss, if you look at
22 their complaints, they have made it very clear that NDMA is
23 inherent in Ranitidine. NDMA is, according to the Plaintiffs,
24 immediate.

25 I would remind the Court at page two of the

1 Plaintiffs' opposition they make the challenge to the generic
2 Defendants very clear. At the top of page two the Plaintiffs
3 state, under both state and Federal law they, meaning the
4 generics, were duty bound to act independently to prevent
5 Plaintiffs' injuries.

6 So, I think it is important to keep in mind the
7 Plaintiffs aren't really talking to your Honor about expiration
8 dates in a vacuum. What they are really saying is that the
9 Defendants are liable because we failed to set a correct
10 expiration date to avoid consumer exposure to NDMA or the risk
11 of cancer. And the regulations make it very clear and the case
12 law makes it very clear that that is a major change that a
13 generic manufacturer cannot make independently or unilaterally.

14 That, too, is an important part of the implied
15 preemption analysis, as your Honor knows from Mensing. The
16 question is, could a generic manufacturer take that step that
17 the Plaintiff is alleging the Defendant should have taken to
18 avoid liability under state law, and do so independently or
19 unilaterally? If it is something they could not do
20 independently or unilaterally, there is impossibility
21 preemption.

22 Under 21 CFR 314.70(b), any change, whether it is a
23 quality related change or a manufacturing, any type of process
24 related change that affects the safety or purity profile of the
25 drug is a major change and it requires FDA approval.

1 In the Gustafson case out of the First Circuit the
2 Court held preempted a claim that implicated the manufacturer's
3 change to a container for prescription eye drops because the
4 Court found that the change affected the purity profile of the
5 prescription eye drops.

6 This idea that a generic manufacturer -- each generic
7 manufacturer on its own could have and should have determined
8 what is a correct expiration date, or a storage condition for
9 that matter, to ensure that consumers aren't exposed to NDMA or
10 the risk of cancer and then slap that date on each package, and
11 everyone can do so on their own independently, unilaterally,
12 and inconsistently, that is just false, and it is inconsistent
13 with the law.

14 *THE COURT:* Response from the Plaintiff.

15 *MR. KELLER:* Thank you, your Honor. It is not false,
16 it is completely consistent with the law. That is why we went
17 through the regulatory regime to demonstrate that each ANDA
18 holder has the right and obligation to set an accurate
19 expiration date for its product.

20 I also want to return to the pleading argument that my
21 friend is making, because it really is not a preemption
22 argument anymore, it is a pleading argument.

23 They are saying that our sole theory is that
24 Ranitidine, the moment it comes off the manufacturing line, is
25 so dangerous it must be pulled from the market. That is what

1 state law requires. They couldn't do that under any theory but
2 misbranding, so they are off the hook on expiration dates.

3 But the complaints are replete with allegations that
4 their expiration dates were inaccurate. To cite just a couple
5 of examples, paragraphs 302, 373, 385, 423, 481, 486, 552 of
6 the master personal injury complaint demonstrate that they had
7 inaccurate expiration dates.

8 Once again, though we say that Ranitidine is
9 dangerous, at the pleading stage we don't say how much time has
10 to lapse before enough NDMA forms in the product to necessarily
11 cause a particular Plaintiff's cancer. We don't say how much
12 is formed through the manufacturing process. We don't say how
13 much is formed as a result of the conditions of the human
14 stomach. We say that some is formed, but we don't have the
15 answers to those scientific questions at this procedural
16 posture.

17 They don't get to flip the rule around on a normal
18 12(b)(6) and say all reasonable inferences should be drawn in
19 their favor and only the theory of liability that lets them off
20 the hook for implied impossibility preemption purposes is the
21 one that the Plaintiffs plead.

22 Yes, we plead that Ranitidine is dangerous, but we
23 also plead that their expiration dates were inaccurate, and we
24 are entitled to all reasonable inferences in our favor on that
25 score, not the other way around.

1 *THE COURT:* Okay. Let me move on to the topic of
2 storage and transportation conditions. This question is
3 directed to the Plaintiffs.

4 Your opposition contains arguments on page 32 relating
5 to storage and transportation conditions. When you allege, for
6 example, in 496(e) and 536(e) of the master personal injury
7 complaint that Defendants failed "to implement appropriate
8 handling instructions and storage conditions," what precisely
9 do you mean by that and where is that explained in the master
10 complaints?

11 Do you mean that any Defendant kept Ranitidine
12 products under the wrong conditions within their own
13 facilities, or do you mean something else?

14 *MR. KELLER:* We mean the former, your Honor. We agree
15 that changing the storage and transport conditions to the
16 extent that it could impact the identity, quality, and purity
17 profile of the drug and pose risk to the ultimate consumer
18 would constitute a major change, but our plausible allegation
19 in the complaints is that this wasn't adhered to.

20 That's why, for example, lots of Courts have held,
21 turning to manufacturing defects, that at this procedural
22 posture we are allowed to proceed. It's not because they could
23 have made major changes to their manufacturing process without
24 preemption. We agree once again that that would constitute a
25 major change. But if they didn't adhere to the manufacturing

1 process that they set forth to the FDA, then there is no
2 preemption and state duties can track Federal law one for one.

3 *THE COURT:* For the Plaintiffs, if a drug product said
4 on the packaging, for example, that the product should be
5 stored between 50 to 80 degrees Fahrenheit, and a drug
6 manufacturer discovered that the product starts to break down
7 into a cancer-causing material at 75 degrees, would the law of
8 any state be satisfied with simply reducing the storage
9 temperatures on the repackaging to a range of 50 to 70 degrees?

10 *MR. KELLER:* That is a great question, your Honor.
11 Yes, that could potentially satisfy the laws of the states, but
12 a different way to satisfy the law would be to simply store it
13 at the low end of the range, which would not be inconsistent
14 with Federal law.

15 If Federal law says store this product between 50 and
16 80, to use I think your Honor's hypothetical, but it doesn't
17 really matter, and state law says store this at 51 degrees,
18 there is no impossibility under those circumstances. State law
19 and Federal law are not identical, but it's not impossible to
20 comply with the state requirement because Federal law gives a
21 choice within a range, and as long as the state requirement is
22 inside of that range, there is no impossibility.

23 *THE COURT:* Wouldn't the state also require better
24 warnings, a redesigned drug, and/or removal of the drug from
25 the market?

1 MR. KELLER: Yes, your Honor, it would also require
2 those different duties. Once again, just because a Defendant
3 can't comply with all state duties doesn't absolve them from
4 responsibility from complying with the ones that are consistent
5 with federal law.

6 So, you are correct, the state would impose additional
7 duties that would potentially be preempted under the Federal
8 regulatory scheme, but that doesn't shield the manufacturer
9 from liability from flouting the duties they could have
10 consistently complied with under both state and Federal law.

11 THE COURT: Again, the primary case that you rely
12 upon, because you have put forth this principle now on several
13 occasions, is -- did you say Bates?

14 MR. KELLER: The Supreme Court's decision in Bates,
15 your Honor, the Eleventh Circuit's decision in Mink from 2017.
16 There are countless other cases that stand for this
17 proposition. It is not some novel point that I am making, this
18 is well established in the case law, but those are two good
19 illustrations.

20 THE COURT: Thanks. All right. Defendants --

21 MR. YOO: Your Honor, may I respond to those points?

22 THE COURT: Briefly, yes.

23 MR. YOO: To the extent the Plaintiffs want to allege
24 that the Defendants failed to adhere to establish storage
25 parameters set by the brand manufacturer and the FDA, that

1 would be an alleged FDCA violation, and that is preempted under
2 337(a), and numerous Courts have so held, including the Sixth
3 Circuit in In Re: Darvocet.

4 As to this idea that if state law were to require
5 Defendants to store their products at the low end of the range,
6 that that would not be inconsistent with Federal law, I think
7 that is false because Federal law, as it states here, provides
8 for a temperature range. And here, Ranitidine is a controlled
9 room temperature product, which means by established guidelines
10 the product is being kept between 20 and two five degrees
11 Celsius, with permitted excursions between 15 and 30 degrees
12 Celsius.

13 If Federal law establishes a range, but state law
14 comes in and says you can't have the benefit of that full
15 range, you get a much smaller range and you have to stay on the
16 shallow end of that, well, that is an inconsistency.

17 Finally, I would like to make an overarching point
18 about Plaintiffs continuing reliance on non-drug cases,
19 non-implied preemption cases. Their whole opposition is
20 reliant on, I believe by my count, 19 medical device express
21 preemption cases, one tobacco case, and one case involving a
22 brand drug. They cited exactly one case involving a generic
23 drug for an entirely irrelevant opposition.

24 Numerous Courts have instructed that express
25 preemption principles and case law should not be used to infect

1 the implied preemption analysis.

2 The Lashley Court out of the Fifth Circuit, Strahorn
3 in the Sixth Circuit, as well as in the Middle District of
4 Florida at the trial Court level, the Guarino decision, the
5 Court stated aptly, "Plaintiffs' focus on the questions
6 involving express preemption is misplaced. Mensing involved
7 conflict preemption which does not depend on limitations of the
8 language in a preemption provision." In other words, no
9 parallel state law claim or alternative theories of
10 liability survive the Supreme Court's ruling in Mensing. That
11 is at page 1292.

12 Thank you, your Honor.

13 *THE COURT:* Thank you.

14 Followup question for Plaintiff. You said that you
15 made a plausible allegation that the Defendant is liable for
16 storage conditions at their facility. What specifically is it
17 that you allege that they did? Was it temperature, something
18 else? What actions did the Defendants take?

19 *MR. KELLER:* That is a fair question. Ashley Keller
20 for the Plaintiffs.

21 To be candid, we don't know the answer to that. The
22 facilities that the Defendants maintain are obviously things
23 that we can only get access to through discovery, but here is
24 why I think our inference is plausible at this procedural
25 posture.

1 As your Honor is aware, the FDA has done limited batch
2 testing of different Ranitidine containing products to see how
3 much NDMA forms over time, and there is a lot of dispersion in
4 the FDA's results. There is always some NDMA that forms, but
5 for reasons that we don't yet know, some Ranitidine containing
6 products have a lot more, and some have comparatively less.

7 I think a plausible inference, again, given that we
8 don't have access to all of these materials yet, is that the
9 storage conditions at the facilities and during transportation
10 and while the product is on the shelves, which would apply to
11 distributors and retailers, are widely disparate, and that is
12 part of the explanation for why different Ranitidine containing
13 products the FDA has found have different amounts of NDMA.

14 We don't need anything more than that at this
15 juncture, your Honor, because, again, we don't have access to
16 these facilities. That, I would think, is what discovery is
17 for.

18 *THE COURT:* Okay, thank you.

19 For the Defendants: Plaintiffs argue on pages 21 to
20 24 of their opposition that some states recognize a claim for
21 failure to warn the FDA, with the duty being owed to consumers.
22 The Court understand the following three things:

23 Number one, Defendants maintain that the cases on
24 which Plaintiffs rely arose in the medical device context and
25 are distinguishable for that reason. And that has been

1 discussed at some length here today.

2 Number two, in *Mensing*, the consumers did not base
3 their claims on the generic drug manufacturers' failure to ask
4 the FDA for assistance, and the Supreme Court stated without
5 providing any citation that, quote, "asking for the FDA's
6 help," end of quote, new quote, "is not a matter of state law
7 concern." *PLIVA, Inc. v Mensing*, 564 U.S. 604, at 619 and 624,
8 2011.

9 The law of the states at issue in *Mensing*, however,
10 "demanded a safer label" and "did not instruct the
11 manufacturers to communicate with the FDA about the possibility
12 of a safer label." That is at 619.

13 Third, if Plaintiffs were alleging a claim of failure
14 to warn the FDA, with the duty being owed to the FDA, that
15 claim would be preempted under *Buckman versus Plaintiffs' Legal*
16 *Committee*, 531 U.S. 341, 2001, as the Eleventh Circuit
17 explained in *Tsavaris versus Pfizer*, 717 F.App'x 874, Eleventh
18 Circuit, 2017.

19 Keeping in mind that the Court understands these three
20 things, explain precisely how, if a state recognized a claim of
21 failure to warn the FDA, with the duty being owed to consumers,
22 the claim would be preempted.

23 In other words, what is the conflict between state
24 law, if state law were with to require warning the FDA under
25 certain circumstances, and Federal law?

1 MR. YOO: Your Honor, I think the Court's
2 question already touched on the answer, and that is, the
3 Mensing Court stated that state law demanded a safer label in
4 that case, it didn't instruct the manufacturers to communicate
5 with the FDA about the possibility of a safer label.

6 So, as the Moreno Court stated in the Eleventh Circuit
7 decision that it doesn't matter what guard you try to put on
8 it, you look at the core allegation and what logically is it
9 that the Plaintiffs are alleging the Defendant should have
10 done, and you use that for the implied preemption analysis.

11 Here, even assuming hypothetically there is a state
12 out there that has fashioned a cause of action based on the
13 Defendant's failure to seek help from the FDA, that still would
14 not absolve a drug manufacturer from alleged liability because
15 the consumer still needs a safer drug or a different warning
16 based on the Plaintiff's allegations.

17 Those are the things where the rubber meets the road,
18 those are the things that either would absolve a Defendant from
19 allegedly liability or implicate a Defendant in alleged
20 liability. Those two things are not things that a generic
21 Defendant can do under the duty of sameness.

22 That is where the conflict exists, your Honor, and
23 that is not going to change no matter how Plaintiffs want to
24 reimagine Mensing or Bartlett or any of the dozens of other
25 cases that have explained the Courts' holdings in those cases.

1 MR. GUGERTY: Your Honor, this is Sean Gugerty for the
2 Defendants. Could I expand very briefly on this one point?

3 THE COURT: Yes.

4 MR. GUGERTY: So, when Mr. Yoo said --

5 THE COURT: Wait, just a minute. Can you turn your
6 volume up?

7 MR. GUGERTY: I will step up a little closer to the
8 mic.

9 THE COURT: Yes, just start over. Thanks.

10 MR. GUGERTY: Yes, your Honor. Just to expand on what
11 Mr. Yoo said, the cases that say that, in your Honor's
12 hypothetical, the ultimate duty owed -- it would be a duty to
13 warn the FDA, but the ultimate duty to the consumer, and there
14 are multiple Courts that have held -- have looked at the
15 analysis as what the manufacturer would need to do to prevent
16 harm to the consumer. If all of the actions are things that
17 are preempted under the principles of *Mensing* and *Bartlett*,
18 then that claim fails.

19 It is a sort of causation focused inquiry. I know Mr.
20 Keller has taken the position that causation is irrelevant to
21 this inquiry, but that is not what the Courts in generic drug
22 cases have done. They have looked at what a manufacturer would
23 need to do to prevent the harm to the consumer. That is the
24 *Drager* case from the Fourth Circuit and also the *Morris v*
25 *PLIVER* case from the Fifth Circuit.

1 Turning this back to the failure to warn the FDA claim
2 from your Honor's hypothetical, the Court in Mensing was very
3 clear that it is inherently speculative about what action the
4 FDA would take if a manufacturer did go to it and did provide a
5 warning, and the Supreme Court, in fact, expanded on this
6 concept at length, referring to the notion of providing a
7 warning to the FDA as starting a speculative mouse tracking
8 about what the FDA might have done.

9 Because, based on that analysis, it is completely
10 unclear and speculative as to whether going to the FDA would
11 prevent the ultimate harm to the consumer, your Honor's
12 hypothetical claim would still be preemptive under the
13 principles of Mensing and Bartlett.

14 Thank you, Your Honor.

15 *THE COURT:* Thank you.

16 *MR. KELLER:* Your Honor, can I respond?

17 *THE COURT:* Yes.

18 *MR. KELLER:* Thank you, your Honor. Ashley Keller for
19 the Plaintiffs.

20 Let me start with a response to Mr. Yoo. This is not
21 some hypothetical state that might impose these duties. As we
22 note in our papers, there are multiple states that do, and
23 California is one of them, so I would commend to the Court the
24 Coleman versus Medtronic case that discusses these principles.
25 We did not make this up.

1 We have to follow state law in an Erie case and we
2 recognize not every state does it, but there are states that
3 have embraced this duty to update the agency even though the
4 duty is ultimately owed to consumers.

5 And to the points that are just made, once again, it
6 is not Mr. Keller arguing that causation is not part of the
7 preemption analysis, that is the Supreme Court's decision in
8 Moore.

9 I would also commend to the Court Judge Watford's
10 concurrence in the Stengel case which I think does a very
11 trenchant job of describing the distinction between the duties
12 on the one hand and the causation inquiry on the other. Judge
13 Watford says, sort of to the last point that was just made,
14 Plaintiffs will often face a difficult causation hurdle because
15 as was just described, it is not easy to know what the FDA will
16 do this with this information even if the manufacturer
17 satisfies its duty.

18 Inherent in Judge Watford's analysis I think is some
19 skepticism that Plaintiffs will succeed on this, and I suspect
20 in many cases, even though there is no preemption of the
21 duties, just on state law causation principles Defendants might
22 be entitled to judgment as a matter of law because Plaintiffs
23 can't establish their causation burden.

24 That is not going to be a problem here, your Honor.
25 We don't have to speculate about what the FDA would have done

1 if the manufacturers had stayed true to their state duties
2 under the laws of states like California. The mouse trap game
3 has already been played, the FDA has instructed them, get
4 Ranitidine off the market.

5 While I think Judge Watford is right, and in a lot of
6 cases causation could be a hurdle, it is not going to be a
7 problem for Plaintiffs in this case, and it is certainly not a
8 problem on a 12(b)(6) motion.

9 MR. YOO: Your Honor, may I respond?

10 THE COURT: Briefly.

11 MR. YOO: Let's look at actual drug cases involving
12 implied preemption instead of medical device cases and other
13 express preemption cases.

14 Plaintiffs have tried negligence and negligence per se
15 causes of action, purportedly under state law, but premised on
16 a variety of theories, many of which the Plaintiffs are trying
17 to invoke here, and in every instance that effort has been
18 rejected.

19 So, in Guarino, Drager, Guarino in the Eleventh
20 Circuit, Drager, a Fourth Circuit decision, Tsavaris, as your
21 Honor mentioned, out of this Court, Allbright also out of this
22 Court, and your Honor's ruling at the State Court level in the
23 Dietrich case, all of those cases, and many more, involve
24 Plaintiff negligence or negligence per se claims based on
25 alleged failure to test, failure to communicate with health

1 care providers, failure to discover latent defects and report
2 those to the FDA, or simply for selling an allegedly misbranded
3 product.

4 In all of those instances the Courts have found, as
5 your Honor did in Dietrich, that these are "alternative
6 theories" in an effort to circumvent Mensing, and they have all
7 been rebuffed at every turn.

8 *THE COURT:* Thank you. Let me ask a followup question
9 for Plaintiffs.

10 You have argued that the Court need not look at all of
11 the duties that state law would impose and that the Court can
12 look at a specific duty that the Defendant could unilaterally
13 do under state law, but you have not brought a cause of action,
14 that is the Plaintiffs have not brought a cause of action that
15 is specific to, for example, expiration dates, nor have
16 Plaintiffs brought a cause of action for failure to warn the
17 FDA under a state law.

18 What you have brought is, for example, strict product
19 liability claims.

20 Why would the Court not look at all the duties imposed
21 under strict liability?

22 *MR. KELLER:* This is Ashley Keller for the Plaintiffs,
23 your Honor.

24 That is another good question, and we believe that the
25 duties we are arguing for here are subsumed within those state

1 causes of action. Again going back to the teachings of Mink,
2 the same cause of action can impose multiple different duties.
3 That was my A, B, and C highly stylized hypothetical. So, we
4 bring claims for strict liability failure to warn, strict
5 liability design defect, negligent failure to warn, negligent
6 design defect, and those are the causes of action that impose
7 these those specific duties. So, the state failure to warn
8 claim encompasses within it, for the brand manufacturers, a
9 duty to change the label on the warnings and precautions
10 section to add a cancer warning.

11 We acknowledge that that duty is not something that
12 the generic manufacturers could can comply with, but the exact
13 same titled cause of action, failure to warn, also includes a
14 duty not to put inaccurate expiration dates on your label.

15 So, we don't have to have, I think, a separate cause
16 of action that says negligent failure to warn, expiration date,
17 negligent failure to warn, warning and precaution section. Our
18 view is, those are all duties subsumed within the overall title
19 of that cause of action under state law.

20 However, if your Honor disagrees with that and doesn't
21 buy my reading of Mink, we, at a minimum, ask for leave to
22 replead because we are more than happy to break these out as
23 separate causes of action if your Honor thinks that is
24 necessary. I don't think it is under state law, but we would
25 be happy to do it in a repleading.

1 *THE COURT:* Okay. Let's see. You may have just
2 answered it in the way you just answered that question. It may
3 be that it is subsumed in the other claims, but I will ask the
4 question as I thought of it coming into the hearing.

5 You argue, this is for the Plaintiffs, on pages 21 to
6 24 of your opposition that claims for failure to warn the FDA
7 of potential hazards, with the duty being owed to consumers,
8 are not preempted, and so I wanted you to point to examples of
9 allegations in your master complaints where you have raised
10 such claims.

11 Is that what you just answered, Mr. Keller, that I am
12 not necessarily going to see failure to warn? Are there
13 certain of the counts, all of the counts that subsume this duty
14 that you are speaking of?

15 I will give you an example to -- an opportunity to
16 respond.

17 *MR. KELLER:* Thank you, your Honor, Ashley Keller for
18 the Plaintiffs.

19 No, I don't think it is all of the counts. The
20 failure to update the FDA pursuant to laws like the one in
21 California, Coleman versus Medtronic, those are failure to warn
22 claims, so it wouldn't be that, for example. It would be
23 failure to warn strict liability and negligent failure to warn
24 are the ones that come to mind. It certainly could be in other
25 counts, I don't want to lock myself into that, but there are

1 other counts where that would not be the duty.

2 *THE COURT:* You have two failure to warns, Count 1,
3 strict product liability failure to warn, and Count 4,
4 negligence failure to warn.

5 *MR. KELLER:* Correct, your Honor, those are the counts
6 that I think capture the heartland of these claims, and if you
7 will just reserve for me the opportunity perhaps later to say I
8 forgot about one, but I think those are the two that are the
9 most relevant for this particular theory.

10 *THE COURT:* Okay. Also for the Plaintiffs, if a
11 generic drug manufacturer learned that its drug caused cancer,
12 would the law of any state be satisfied with the manufacturer
13 simply telling the FDA?

14 Following up on that after you answer that question,
15 why wouldn't the state also require better warnings, a
16 redesigned drug and/or removal of the drug from the market?

17 *MR. KELLER:* Thank you, your Honor, Ashley Keller for
18 the Plaintiffs.

19 I sort of view that as a variance of a question I
20 tried to answer before, which is, I don't think the law of any
21 state would be fully satisfied by just updating the FDA. To
22 the extent a state did impose that duty as one of several that
23 manufacturers should take, they can't get out from
24 responsibility for breaching that duty just because there were
25 other duties they also breached because Federal law didn't

1 allow compliance.

2 In that particular hypothetical, your Honor, where
3 they know that a drug causes cancer, and they don't provide
4 that information to the experts at the FDA to make a
5 determination, that, I think, runs squarely into our
6 misbranding theory, where I do think state stop selling duties
7 and Federal law are perfectly consistent with each other, and
8 once again, our position is that Bartlett left this question
9 open for the Court to decide in the first instance.

10 *THE COURT:* Okay. Turning to the Magnuson-Moss
11 Warranty Act for the Plaintiffs, Defendant argues at pages 32
12 and 33 of the Motion to Dismiss that Plaintiffs' Magnuson-Moss
13 Warranty Act claims must be dismissed because, under 15 U.S.C.
14 Section 2311(d), the act is "inapplicable to any written
15 warranty the making or content of which is otherwise governed
16 by Federal Law." Counsel for Defense has made that point also
17 here today.

18 You argue on page 33 of your opposition, that is the
19 Plaintiffs, that this argument is "inappropriate for a Rule 12
20 motion."

21 Why is the argument and a ruling on the argument
22 inappropriate at this stage of the litigation?

23 *MR. KELLER:* A couple of points, your Honor. Ashley
24 Keller again for the Plaintiffs.

25 We cite a California case for that proposition, and we

1 do allege in the complaints that there may have been other
2 statements that were made with respect to these products that
3 weren't necessarily just the label and weren't fully regulated
4 by Federal law, and that is where I think summary judgment
5 could be the more appropriate procedural posture to dispose of
6 these claims.

7 But then coming back to the core argument, first and
8 foremost, the provision of Federal law that your Honor read
9 isn't a preemption provision, it is just a carve out from
10 Mag-Moss. An express warranty that's completely regulated by
11 Federal law can't serve as the anchor claim to establish a
12 Mag-Moss violation, but by its terms, that provision only
13 applies to written warranty claims.

14 We also, of course, have implied warranty claims, and
15 it is worth noting here, the brand manufacturers don't even
16 bother to move, I believe, to dismiss the Mag-Moss claims.
17 They don't incorporate by reference any of the other arguments
18 from the other Defendants on this.

19 I suspect, and you can ask them when it's their turn,
20 that they made a tactical decision to just be intellectually
21 honest with the Court, because they are not moving to dismiss
22 our failure to warn labeling based claims because they
23 recognize at this procedural posture that the labels can serve
24 as a basis for a warranty that was breached, there is an
25 implied warranty of merchantability that comes along with those

1 express warranties and that can serve as the Mag-Moss anchor.

2 If your Honor agrees with us at least on expiration
3 dates, the same logic would apply to the generic manufacturers.
4 They could have had a label that warranted the safety of the
5 product was actually accurate. They didn't do it. Though the
6 express warranty itself couldn't get us a Mag-Moss claim, the
7 implied warranty of merchantability that comes along with
8 stating that on the label can serve as a basis for the Mag-Moss
9 claim.

10 *THE COURT:* A followup question for Plaintiffs on the
11 Mag-Moss.

12 15 U.S.C. Section 2311(d) makes the Magnuson-Moss
13 Warranty Act "inapplicable to any written warranty the making
14 or content of which is otherwise governed by Federal law." You
15 argue at page 34 of your opposition that even if this language
16 forecloses Magnuson-Moss Warranty Act claims relating to
17 express warranties -- this may go to what you just said, but I
18 want to give you an opportunity to answer the question that I
19 had crafted in advance of the hearing.

20 Even if this language forecloses the Magnuson-Moss
21 Warranty Act claims related to express warranties for products
22 with FDA regulated labeling, the language does not foreclose
23 claims relating to implied warranties.

24 Aren't implied warranty claims tied to the labeling,
25 in this case labeling that the FDA had approved? For example,

1 California's implied warranty statute defines implied warranty
2 of merchantability as meaning, among other things, that the
3 product conforms to the promises or affirmations made on the
4 label. That is California Civil Code Section 1791.1(a).

5 Under any state's law can an implied warranty claim be
6 separated and independent from the label?

7 MR. KELLER: Thank you, your Honor. Ashley Keller
8 again for the Plaintiffs.

9 I do think that my previous answer largely addresses
10 that, but I can amplify just a little bit. I definitely think
11 that the implied warranties can be keyed off of the label, so
12 you would have to agree with us, if we were focused only on the
13 label, that there is something that the generic in this
14 argument, or the brand manufacturers with respect to their
15 argument, could have done to make the label more accurate.

16 It is also true that the label itself would be an
17 express warranty which is completely regulated by Federal
18 law and so that couldn't serve as the anchor, but the implied
19 warranty claim, as your Honor just read it, under California
20 law, which is keyed off of the label, is outside of the carve
21 out, it is implied, not written.

22 So, even though there is a relationship between the
23 implied warranty claim turning on the label, and the express
24 warranty claim, which is the label, I think the implied
25 warranty claims can serve as that anchor to allow the Mag-Moss

1 claim to proceed, but you still have to do the preemption
2 analysis to make sure that there is something that the
3 manufacturer could have changed on the label.

4 *THE COURT:* Okay. All right. Thank you. That
5 concludes the first motion, 1582. I want to thank all counsel
6 for your presentations and for answering the Court's questions.
7 I am most appreciative of that. You can turn your videos and
8 audios off, although some of you may be coming back on.

9 We will do this one before the lunch hour and then
10 we'll break for our lunch break. 1583 is the next motion that
11 the Court will hear, and this is the distributor Defendants'
12 Rule 12 Motion to Dismiss on the ground of preemption and
13 incorporated memorandum of law.

14 If we could have counsel for Defense and counsel for
15 Plaintiff.

16 *MR. KAPLAN:* Good morning, your Honor, Andrew --

17 *THE COURT:* I'm sorry about that, just Defense. Go
18 ahead and introduce yourself.

19 *MR. KAPLAN:* Andrew Kaplan, I represent Cardinal
20 Health, Inc. and Medicine Shop International, Inc. in this
21 litigation and I am here today to argue on behalf of all of the
22 distributors for their Motion to Dismiss on the grounds of
23 preemption, Docket Entry 1583.

24 *THE COURT:* You have 15 minutes. Do you want to
25 reserve any or use it all on the front end, and do you want any

1 warnings?

2 *MR. KAPLAN:* Yes, your honor. I actually have two
3 requests. I don't think I will use near my entire time, so I
4 would like to reserve five minutes, but because of the overlap
5 between the retailer and pharmacy and the distributor briefs,
6 the issue of the Drug Supply Chain Security Act, which is in
7 both of the briefs and is essentially the same, Ms. Kapke, who
8 represents the retailers and pharmacies, is going to address
9 that issue.

10 I would ask that if I have time remaining from my 15
11 minutes that that be reserved for Ms. Kapke, because she will
12 be arguing that issue on behalf of both sets of Defendants.

13 *THE COURT:* Okay. It might help you to know this,
14 that I am going to defer any questions specifically for
15 distributors until after I hear the presentation from the
16 retailer and pharmacy on their motion at 1584, in which case I
17 will hear presentation then I will ask all counsel from this
18 motion and that motion to come on for any questions.

19 If that helps you in terms of how you want to include
20 other counsel for purposes of your argument here, just keep
21 that in mind.

22 *MR. KAPLAN:* Thank you.

23 *THE COURT:* Okay. So I will let you begin, then.

24 *MR. KAPLAN:* Thank you, your Honor. May it please the
25 Court.

1 Distributors have a unique role in the supply chain.
2 Distributors do not design, manufacture, or label
3 pharmaceuticals, nor are they permitted to do so because they
4 do not hold an NDA like the brand named Defendants, and they do
5 not hold an ANDA like the generic Defendants. Plaintiffs don't
6 allege otherwise. Distributors do not diagnose medical
7 conditions, nor do they write or fill prescriptions.
8 Plaintiffs do not allege otherwise.

9 Distributors do not in the normal course have any
10 contact with the consumers of the products that they
11 distribute. Again, Plaintiffs do not allege otherwise.

12 Distributors simply serve as a passthrough,
13 distributing product between pharmaceutical manufacturers and
14 retailers. Distributors' uniquely insulated role in the supply
15 chain means that Plaintiffs' arguments and theories simply do
16 not apply to them and necessitate the dismissal of Plaintiffs'
17 claims against them with prejudice.

18 You have heard a lot over the past day plus, all of
19 these arguments apply derivatively to the distributors, so to
20 the extent a manufacturer cannot be liable, neither can the
21 distributor.

22 Even if the Court were to deny any part of the motions
23 against the companies that designed and manufactured the
24 product at issue, the claims against the distributors should
25 still be dismissed.

1 Your Honor, the distributors who are named only in the
2 master personal injury complaint and the consumer class action
3 complaint have four high-level arguments for preemption.

4 First, under the Supreme Court's precedent in *Mensing*
5 and *Bartlett*, impossibility preemption bars all claims against
6 the distributors. This eliminates all counts in both
7 complaints against the distributors.

8 Second, the express preemption provision in Section
9 379(r) of the Federal Food, Drug and Cosmetic Act expressly
10 preempts all economic loss state law claims against
11 distributors related to OTC Ranitidine products. And I should
12 mention that that issue is going to be covered in the brand
13 argument by Ms. Eisenstein and Ms. Horton later.

14 Third, the Drug Supply Chain Security Act expressly
15 preempts all state law claims based on nonidentical
16 requirements for prescription Ranitidine.

17 And finally, the Magnuson-Moss Warranty Act claims,
18 Count 3 of the consumer class complaint, fail because the
19 necessary underlying warranty claims are preempted, and as just
20 discussed, the act prohibits claims related to written
21 warranties that are governed by Federal law, as they are here
22 with the Federal Food, Drug and Cosmetic Act.

23 Turning to *Mensing* and *Bartlett*, generics counsel
24 covered this issue well so I won't repeat most of what was
25 discussed, but the premise is that where the Defendant cannot

1 comply with state law and Federal law, there is impossibility
2 preemption. Under Mensing and Bartlett, it was established
3 that where a Defendant cannot act unilaterally to meet the
4 alleged duty without violating the FDCA, then the claim is
5 preempted and there is no loophole for arguments that the
6 Defendant could just stop selling the product or the Defendant
7 could just pay fines and compensation.

8 In those two Supreme Court cases, the Court made clear
9 that the failure to warn based claims and the design defect
10 based claims were preempted against generic drug manufacturers
11 because they did not hold the NDA, only an ANDA. They were
12 required to have the same formulation of the drug and the same
13 labeling for the drug as the NDA holder. They had no ability
14 to unilaterally change the design or labeling with their ANDA.

15 The distributors are even one more step removed from
16 the ability to impact any changes to the drug because, not only
17 do they not hold an NDA, but they do not hold an ANDA either.
18 The distributors may not do anything to the drug. They are not
19 allowed to change the warnings and labelings. They are not
20 allowed to change the formulation or design, and they are not
21 allowed to change the storage temperatures for the drug.

22 For this reason, Courts have held that claims against
23 distributors for allegedly defective pharmaceuticals are
24 preempted under the principles of Mensing and Bartlett. We
25 have cited at least six cases where Courts have held that

1 downstream Defendants like distributors or retailers and
2 pharmacies are subject to the same preemption principles
3 articulated in Mensing and Bartlett.

4 Plaintiffs' only response to this appears to be the
5 placement of strict and absolute liability, but the Supreme
6 Court rejected this end run around preemption in the Bartlett
7 decision. There the Court stated "but respondent's argument
8 conflates what we will call a strict liability regime in which
9 liability does not depend on negligence, but still signals the
10 breach of a duty, with what we call an absolute liability
11 regime in which liability does not reflect the breach of any
12 duties at all, but merely serves to spread risk." That is 570
13 U.S. at 481.

14 The Bartlett Court then held that the strict liability
15 claim at issue was preempted.

16 While the Supreme Court declined to address the
17 hypothetical absolute liability scheme, as the Court noted, it
18 is unlikely that one exists. Plaintiffs have neither pled an
19 absolute liability cause of action, nor have they even
20 identified such a state law claim that would allow them to do
21 so.

22 For those reasons, all of the claims against the
23 distributors must be dismissed under Mensing and Bartlett.

24 I will turn briefly to the Magnuson-Moss Warranty Act
25 claims. Again, I think those issues were almost fully

1 addressed with respect to the generics' arguments, but the
2 basic principle applies as well to the distributors. To state
3 a claim under the Magnuson-Moss Warranty Act, a Plaintiff must
4 state a valid state law breach of warranty claim. The
5 Plaintiffs do not dispute this in their briefs.

6 So, if the warranty claims fail against distributors,
7 so too must the Magnuson-Moss claims.

8 As previously discussed, because the distributors do
9 not hold the NDA or ANDA for the drugs they distribute, they
10 lack the legal capacity to change their formulations or warning
11 labels, and thus are immune from the claims for alleged design
12 defects or failures to warn under Mensing and Bartlett.

13 Federal Courts have applied this principle to exclude
14 warranty claims similarly premised on allegedly unsafe drugs.
15 We cite the Strahorn decision and the Moore decision in the
16 briefing.

17 As discussed, the Magnuson-Moss Warranty Act does not
18 apply to written warranties controlled by Federal law.
19 Therefore, any express warranties that could be subject to FDA
20 regulation are not a proper basis for the Magnuson-Moss claim
21 and implied warranties, to the extent that they are
22 derived from what is written, are also not a proper basis for
23 the Magnuson-Moss claim.

24 I will note that, I think it is in the consumer class
25 complaint, there are all -- 52 times, I believe, where the --

1 excuse me -- where the Plaintiffs repeated the same phrase, the
2 Defendants breached their implied warranty of merchantability
3 because their products were not in merchantable condition when
4 sold, were defective when sold, do not conform to the promises
5 and affirmations of fact made on the products' containers or
6 labels. They are directly tying their implied warranty claims
7 to the labeling.

8 For these independent reasons, the Magnuson-Moss
9 claims fail as well against the distributors.

10 I will just note that I believe I heard Mr. Keller say
11 earlier that there were statements -- there could be statements
12 that wouldn't be impacted by the Federal statutory regime that
13 we argue under 2311(d) which would preclude such Magnuson-Moss
14 claims, but I am not aware, having looked through the lengthy
15 complaints, of any allegation that the distributors made any
16 other statements about the products other than what is on the
17 product that they pass through from the manufacturer to the
18 retailer.

19 With that, I will reserve the rest of my time. Thank
20 you, your Honor.

21 *THE COURT:* Thank you. And from the Plaintiffs. Mr.
22 Kaplan can come off, and Mr. Keller can come on to argue for
23 the Plaintiffs.

24 *MR. KELLER:* Thank you, your Honor, Ashley Keller on
25 behalf of the Plaintiffs. Your Honor, I will be brief, I don't

1 need to use my entire 15 minutes.

2 I think it is prudent that we lump together the
3 distributors and the retailers for purposes of Q and A because
4 I think a lot of the arguments overlap. So, I am about to
5 touch on a point that perhaps Mr. Kaplan's colleague is going
6 to address in the retailer motion, but I did want to revisit
7 misbranding, not to repeat the arguments that we already
8 extensively went over in the generic presentation, but to talk
9 about a twist that the retailers and distributors introduced
10 that they say is specific to that category of Defendants.

11 Very quickly once again, the misbranding theory that
12 we pursue says that they have to stop selling a dangerous drug,
13 and we argue that, under the FDCA, the definition of
14 misbranding and the Supreme Court's footnote in Bartlett, that
15 remains available and not preempted.

16 So, state and Federal duties are the same, and those
17 duties apply up and down the chain of distribution. So, it's
18 not just the duties under Federal law that applies to the
19 manufacturers, it also applies to distributors and retailers.
20 That is under 21 U.S.C., Section 331(a), (c) and (g) again.

21 The twist that the distributors and retailers
22 introduce in their papers is they say that there is a good
23 faith exception under the FDCA that alleviates any
24 responsibility for them and shields them from the duties
25 imposed by Federal law, and that is the point that I want to

1 hit with respect to this category of Defendant because it is
2 not correct under the FDCA.

3 Once again, the duties are created by Section 331.
4 There is no good faith exception in that provision of Federal
5 law, there is no dispensation, there is no discrimination
6 between categories of Defendants. It is an absolute statement
7 of the duties created by Federal law, you must not sell a
8 misbranded drug, period. That applies to the distributors and
9 retailers.

10 As the Supreme Court noted in the Datareich (phon)
11 case that we cited from Justice Frankfurter, this is a strict
12 liability criminal offense, it doesn't even require mens rea
13 for a criminal conviction. The good faith exception is not
14 contained in Section 331, it is contained in Section 333, 21
15 U.S.C., Section 333.

16 Section 333(a)(1) creates the criminal penalties that
17 violators are subjected to under the statute. You can go to
18 jail for a year or pay a thousand dollar criminal fine, or
19 both.

20 The good faith exception that my friends from the
21 retailers and distributors cite comes from Section 333(c),
22 which says the penalties under subsection (a)(1), it references
23 that single paragraph, "shall not apply to someone who took a
24 misbranded drug in good faith in interstate commerce."

25 They then say, as a result of that, any state that

1 does not have a good faith exception read in to its civil
2 liabilities are somehow violating the supremacy clause and
3 those causes of action would be preempted. That once again
4 confuses the lesson of in Moore and cases like Regal, your
5 Honor, which says that preemption is about comparing duties,
6 not the punishments or remedies.

7 Specifically here where the carve out, where the good
8 faith exception is so limited in its scope, it by its plain
9 terms doesn't apply to our causes of action.

10 I know this is obvious to the Court, but to make the
11 point squarely, we are here as Plaintiffs in a civil
12 proceeding. We are not pretending to act as private Attorneys
13 General on behalf of the states enforcing their penal codes.
14 We are not seeking to impose on these Defendants a year in jail
15 or a thousand dollar criminal fine. We are seeking civil
16 damages as redress for the cancer and other injuries that
17 Plaintiffs have suffered.

18 So, there is no good faith dispensation in the statute
19 for civil liability and to confirm that that is true, your
20 Honor, you can look at the very next section of the statute, 21
21 U.S.C. Section 334.

22 This allows the Government to seek civil remedies
23 against retailers and distributors through an injunction to
24 seize their misbranded drugs. It doesn't matter what their
25 knowledge was. It doesn't matter that they took in good faith,

1 it doesn't matter that they paid good money for the drugs and
2 had good title. The Government is to ensure the safety and
3 efficacy of the drugs in interstate commerce and civil
4 liability can be imposed without any good faith dispensation.
5 So, the good faith exception is not a work around to our
6 misbranding theory.

7 The final point that I want to hit, your Honor, goes
8 back to our negligence claims to demonstrate they survive. I
9 don't think I heard my friend argue otherwise, although of
10 course they do in their papers.

11 I would point your Honor to paragraph 407 in the
12 master personal injury complaint that says that FDA testing has
13 confirmed that the inadequate storage and transportation
14 conditions are responsible for some of the high levels of NDMA
15 contained in these products.

16 Once again remembering the pleading standard that we
17 are subjected to, we don't yet have access to all of the
18 factual materials that we would need to confirm this well
19 pleaded allegation. We don't know whether the distributors
20 left Ranitidine on a hot truck in the Arizona desert during the
21 summer for extensive periods of time creating temperature
22 ranges that vastly exceeded those on the label. We don't know
23 if retailers did the same thing in your hometown of South
24 Florida during the hot summer months before they put the
25 Ranitidine on the air conditioned shelves.

1 So, based on the information we have today and once
2 again the dispersion that we noted from FDA batch testing that
3 shows that NDMA does not form at a uniform rate through all of
4 the batches that thy have tested, it is plausible at this
5 procedural posture that distributors and their retailer
6 counterparts didn't engage in proper storage and transportation
7 conditions and that would support a negligence claim because
8 the duties, of course, as every first year law student knows,
9 for negligence is to behalf as a reasonably prudent person
10 would.

11 It is obviously reasonably prudent when you are
12 dealing with a pharmaceutical product that's been approved by
13 the FDA and has specific ranges of temperature and other
14 conditions like exposure to light put on the labels, that those
15 conditions have to be satisfied and met by distributors and
16 retailers in order to ensure that consumers don't get a
17 dangerous product.

18 So, there wouldn't be any preemption that would
19 prevent these negligence claims from proceeding if the
20 retailers and distributors were flouting the instructions that
21 the FDA and the manufacturers put on the labeling and packaging
22 of these products.

23 I will pause there, your Honor, and go off screen and
24 await the retailer presentation.

25 *THE COURT:* Thank you. Any rebuttal from the

1 Defendant?

2 MR. KAPLAN: Your Honor, very briefly. I will reserve
3 the issue of the conveyed exception for the retailer and
4 pharmacy counsel to address that in their briefing.

5 But briefly on the issue of misbranding, that was
6 covered at length in the generics argument, so I won't rehash
7 all of the arguments there. The distributors, as I said
8 earlier, are one step -- another step removed from this
9 process. They can't change the labeling, they can't change the
10 design, they can't change the storage requirements, they can't
11 change the expiration dates.

12 It is the very definition of a conflict with Federal
13 law for the distributors to make a unilateral stability
14 determination apart from the FDA and apart from the NDA holder,
15 and handle the drug in accordance -- in a way that is different
16 than what the FDA has required and in a way that could cause
17 adulteration of the product.

18 So, we agree with the generics that this exception
19 that the Plaintiffs are arguing to try to get around the
20 Bartlett and Mensing decisions is not viable, but to the extent
21 it were theoretically viable, it wouldn't apply here to
22 distributors.

23 Thank you.

24 THE COURT: Thank you very much. That concludes the
25 morning session.

1 We will resume at 1:15. It is about twelve o'clock
2 now, 12:02. We will resume at 1:15. We will have the final
3 two motions of the day heard, 1584 and 1580. As I said, after
4 presentations on 1584, I will invite all counsel who have
5 argued 1583, as well as 1584, to be on the screen to address
6 any questions that the Court may have.

7 So, with that, have a nice lunch, and stay on the Zoom
8 as we discussed yesterday. Don't leave the meeting if it is
9 possible, just turn your video and audio off. This makes it
10 easier on those who are admitting people. And we will see you
11 back at 1:15. Thank you.

12 (Thereupon, a luncheon recess was taken.)

13 *THE COURT:* Okay, welcome back, everybody. If we
14 could have the attorneys for 1584, which is the retailer and
15 pharmacy Defendants' Rule 12 Motion to Dismiss on the grounds
16 of preemption and incorporated memorandum of law.

17 We will have counsel introduce themselves, and I
18 understand you have allotted 15 minutes for yourselves in
19 conjunction with the Court and discussions between counsel, so
20 let me know how you want to break that up, and whether you want
21 any warnings.

22 *MS. JOHNSTON:* Good afternoon, Sarah Johnston on
23 behalf of the retailer and pharmacy Defendants. Also with me
24 is my colleague, Kara Kapke, also for the retailer and pharmacy
25 Defendants.

1 I will be speaking to the substantive issues set out
2 in the Motion to Dismiss and Ms. Kapke will be speaking to the
3 Preemption and Securities Act. She will be doing it on behalf
4 of the retailer, pharmacy Defendants, and distributor
5 Defendants.

6 And in terms of timing, I wanted to follow up on a
7 question that Mr. Kaplan asked when he was speaking for the
8 distributors, which is whether his remaining time could be
9 allocated to Ms. Kapke for the DSCSA arguments. They will be
10 on behalf of both groups of Defendants. I believe the Court
11 was amenable to that, I want to make sure before we allocate
12 time.

13 *THE COURT:* Right. Yes, that is a fair question.

14 The Defendants did have from the last motion five
15 minutes and 11 seconds left of their allotted time and the
16 Plaintiffs had eight minutes and four seconds left. So I will
17 give both sides the remaining time to be fair.

18 So you have 15 minutes, plus five minutes and 11
19 seconds. You have 20 minutes and 11 seconds, and so you can
20 divide it up among yourselves however you want. Just tell me
21 whether you want any rebuttal period so I can let you know, and
22 whether you want any warnings.

23 *MS. JOHNSTON:* Sure. I think on my part, I probably
24 need eight or nine minutes maximum, and Ms. Kapke I think will
25 need roughly the same, and we will reserve whatever is left for

1 rebuttal if necessary.

2 *THE COURT:* Okay. So I will let you run through, if
3 you use all of your time you won't have any rebuttal. If you
4 don't use your time, you will have rebuttal. Okay. That
5 sounds straightforward.

6 Okay, you may proceed.

7 *MS. JOHNSTON:* Good afternoon again, your Honor, Sarah
8 Johnston on behalf of the retailer and pharmacy Defendants.
9 For ease of efficiency, I will be referring to both groups as
10 the retailers. We will distinguish among them as necessary
11 throughout the argument.

12 As the Court and counsel know, we have spent a fair
13 amount of time over the last two days, and particularly today,
14 addressing the issues of Mensing and Bartlett preemption,
15 because the -- as set forth in the generic and distributors
16 briefs, it is my goal not to retread over a lot of that ground,
17 but there are a few areas that warrant revisiting, especially
18 since they pertain to the retailer Defendants.

19 And since they are preempted as to this group of
20 Defendants, I think it is important that we explore that with
21 an eye towards the retailers for two reasons.

22 The first is, as we heard yesterday during the
23 pleading arguments, the complaints fail to distinguish among
24 the different levels of supply chains as to the allegations of
25 liability.

1 And second, and I think this is more important, what
2 the Plaintiffs here are asking for as to the downstream
3 Defendants is to do something that has never been done before
4 in the context of pharmaceutical product liability MDLs, and
5 that is to extend liability beyond manufacturers and into the
6 entire supply chain and thereby holding dozens of retailers,
7 pharmacies, and distributors liable, or potentially liable for
8 an alleged latent defect in a drug.

9 So, jumping into that, the master complaints, as Mr.
10 Petrosinelli explained yesterday, at most, put the 90 or so
11 Defendants here on notice that Plaintiffs are pursuing claims
12 related to an alleged latent defect in Zantac and basically
13 that, with minimal exceptions, everybody is on the hook for it.

14 Despite the fact that common sense would inform the
15 difference between a manufacturer and a pharmacy, Plaintiffs
16 make the same general allegations fairly indiscriminately
17 against all Defendants, including the retailer Defendants, with
18 the only distinction as to the retailers being that the
19 retailers are not part of the so-called knowledge Defendants.

20 In other words, the retailers are -- I think this is
21 identified in paragraph 360 of the master PI complaint, but the
22 retailers are the sole group of Defendants here who are not
23 even alleged to have knowledge of the risk of NDMA formation in
24 Zantac from its inception.

25 Setting that aside and working through the noise of

1 the complaints, as we heard from both the generics and the
2 distributors today, the claims basically break down into one of
3 two arguments, the first being that Zantac is inherently
4 defective because of its molecular instability and that that
5 leads to the formation of NDMA, and/or that the warnings are
6 inadequate because they fail to inform of that risk.

7 For the same reasons that we have heard from the other
8 Defendants today, those claims are also preempted as to the
9 retailer Defendants, and that's because the analysis here turns
10 on whether the retailers could have done anything independently
11 with respect to the design or the warnings of Zantac or
12 Ranitidine which, as we now know, retailers cannot do.

13 The retailers, like the distributors, never applied to
14 FDA for approval of any formulation of Zantac or Ranitidine.
15 That means the retailers, as non NDA holders or even ANDA
16 holders here, have no ability to effect change in the design or
17 the warnings of Zantac or Ranitidine.

18 This is the principle of Mensing and Bartlett and this
19 is the precise reason why these claims are preempted. In a
20 perfect world that stops the discussion, it ends the analysis.

21 This is the motion that we put before the Court, but
22 unfortunately, because it seems the Plaintiffs have recognized
23 the fundamental challenges of trying to expand potential
24 liability so deep into the rest of the supply chain, they now
25 appear to have changed course.

1 So, while the master complaints, and particularly the
2 master PI complaint asserts 11 causes of action against the
3 retailers related to the design and warnings associated with
4 Ranitidine, they appear to have abandoned those claims as to
5 the downstream entities for purposes of their opposition.

6 I will quote from their opposition at page two where
7 they state, "the basis of state law liability is not the
8 failure of a distributor, retailer, or pharmacy to redesign
9 Ranitidine or modify its label. No Court or legislature
10 expects a retailer to detect and fix defects in drugs any more
11 than in Coca-Cola or a lawnmower." They go on at page 13 to
12 say Plaintiffs, quote, "do not dispute that manufacturers, not
13 retailers, design, manufacture, and label regulated drugs."

14 So, in other words, Plaintiffs concede that they have
15 no viable nonderivative claim of product defect against this
16 group of Defendants, and said slightly differently, that means
17 that any massive litigation formed by the JPML for the purpose
18 of determining the alleged defect in Zantac, Plaintiffs concede
19 that they don't have product liability claims against the
20 downstream Defendants.

21 This is borne out in their opposition. They do not
22 respond to any of the authority that is cited in our briefs.
23 That includes the Smith case that we cite from the Southern
24 District of Florida. And they also don't cite any preemption
25 authority to the contrary.

1 This is important given that the expansion they are
2 suggesting is so broad that the preemption analysis apparently
3 is just thrown away, and that, also, should end this
4 discussion, but unfortunately, instead of accepting Bartlett
5 and Mensing for what they stand for and proceeding against
6 manufacturers of the drug at issue and admitting the claims
7 against the retailers and distributors are nonstarters,
8 Plaintiffs have decided instead to get creative, and I think
9 incorrectly creative, but creative, and that is in their
10 opposition.

11 While the Plaintiffs concede that they don't have
12 product liability claims against the retailer Defendants, they
13 have now advanced for the first time this novel argument that
14 preemption is completely inapplicable here because these
15 Defendants, the retailers, were, in Plaintiffs' words,
16 absolutely liable.

17 This is a novel, untested theory, it is not recognized
18 by any Court and it shouldn't be entertained here, particularly
19 given the issues at stake in this litigation.

20 In short, Plaintiffs shouldn't be rewarded for
21 attempting to create law out of thin air even if it is
22 creative, and particularly when to do so would upend preemption
23 law that we have been discussing all day, that preemption law
24 that applies in drug litigations and MDLs like this one, and
25 the effect of which would render Bartlett and Mensing and its

1 preemption principles basically toothless.

2 With that, I am going to turn to Ms. Kapke and allow
3 her to address the Drug Supply Chain Security Act and then we
4 may have some discussion on rebuttal, and happy to answer any
5 questions. Thank you.

6 *MS. KAPKE:* Kara Kapke presenting the argument on
7 behalf of pharmacies and distributors under the Drug Supply
8 Chain Security Act. Thank you. May it please the Court.

9 Although Courts have not previously considered the
10 import of the preemptive scope of the Drug Security Act, that
11 is only because, as my colleague, Ms. Johnston, explained,
12 Plaintiffs rarely sue pharmacies for alleged defects in
13 prescription drugs.

14 The preemption analysis under the Drug Security Act is
15 straightforward and it compels the conclusion that claims
16 against pharmacies and distributors here relating to
17 prescription Ranitidine are preempted under Federal law.

18 Any express preemption analysis has two parts. First,
19 what are the requirements Federal law imposes? And second, how
20 do the state law requirements relate to the Federal
21 requirement?

22 Plaintiffs' opposition focuses entirely on that first
23 part of the analysis. In their response Plaintiffs claim that
24 the act only preempts, quote, "tracing products through the
25 distribution system," which, in their view, means only knowing

1 where Ranitidine was and where it came from.

2 That is contradicted by the consumer class complaints'
3 allegations that distributors and pharmacies were obligated
4 under the act to quarantine and investigate potentially
5 illegitimate drugs. That is at paragraphs 675 and 669 of
6 docket number 889.

7 Regardless of that allegation, what we must do is look
8 at the text of the statute, and the Drug Security Act expressly
9 defines what tracing products through the distribution system
10 means, and that necessarily includes the entirety of the act's
11 requirements. If you look specifically at the test of the
12 statute, both the preemption clause and the savings clause, it
13 explains that tracing products includes any requirements with
14 respect to transaction information, verification, or
15 investigation.

16 So, any requirement relating to verification or
17 investigation necessarily falls within the scope of the
18 preemption clause, contrary to Plaintiffs' argument.

19 Pharmacies and distributors are required to capture
20 information necessary to investigate a suspect product and
21 implement systems for quarantining suspect product.

22 But tracing products also by definition includes
23 requirements with respect to transaction statements. Both
24 pharmacies and distributors are forbidden from accepting a
25 shipment of prescription Ranitidine unless manufacturers

1 provide a transaction statement along with that shipment. That
2 transaction statement requires the manufacturer to state that
3 it is authorized to ship the drug, that it did not knowingly
4 ship a suspect or illegitimate product, and that it had systems
5 and processes in place to comply with verification
6 requirements.

7 Let me repeat that. Pharmacies and distributors
8 cannot accept drug shipments unless the manufacturer states
9 that it did not knowingly ship a misbranded product. That is
10 really key here because Plaintiffs' claims against the
11 pharmacies and distributors seek to require more from this
12 transaction statement.

13 Plaintiffs' claims seek to insist that the transaction
14 statement include a statement from the manufacturer that the
15 product was not, in fact, misbranded. Plaintiffs'
16 claims insist that the pharmacies or distributors investigate
17 whether the drug was misbranded or suspected to be misbranded
18 before accepting shipment, but that very same information is
19 already discussed on the transaction statement.

20 In defining what must be included on a transaction
21 statement, Congress provided exactly what level of
22 investigation it sought to require from pharmacies and
23 distributors, and in turn, what it expected pharmacies and
24 distributors to require from manufacturers before accepting
25 shipments from them.

1 The only thing that Congress required is a statement
2 that the manufacturing party and subsequent trading partners
3 did not knowingly ship a misbranded product. Plaintiffs'
4 claims seek to require more, and they are therefore preempted.

5 A final quick point on the second prong of any
6 preemption analysis, which is how the Federal requirement
7 relates to the state law requirement.

8 Here again you must look to the explicit text of the
9 statute, and the Drug Security Act preempts any state law
10 requirements which are inconsistent with, more stringent than,
11 or in addition to any requirements applicable under the
12 statute. The more stringent than language is key. That is
13 broader than the express preemption provisions in the medical
14 device amendments or the Federal Insecticide and Fungicide and
15 Rodenticide Act and the Federal Metal Inspection Act, to give a
16 few examples. All of which only reference requirements that
17 are "inconsistent with or in addition to Federal law."

18 Here, anything more stringent than that transaction
19 statement requirement is preempted. State common law duties
20 that require pharmacies and distributors to investigate
21 manufacturers more than reviewing the transaction statement and
22 confirming that the manufacturer did not knowingly
23 distribute suspect or misbranded drugs are certainly more
24 stringent than what the Drug Security Act preempts and are thus
25 preempted.

1 I will reserve the remainder of my time for rebuttal
2 to address Plaintiffs' responses and Mr. Keller's arguments
3 both forthcoming and the remaining responses.

4 *THE COURT:* Thank you. You used about 13 minutes and
5 23 seconds, so you do have remaining time for your rebuttal.

6 So, now if we could have Mr. Keller, who is on the
7 screen, to respond from the Plaintiffs.

8 *MR. KELLER:* Thank you, your Honor. Good afternoon,
9 Ashley Keller on behalf of the Plaintiffs.

10 I think it is always useful, where possible, your
11 Honor, to start with places of common ground.

12 So, I want to concede that we agree with our friends
13 that they are not NDA holders, they are not ANDA holders, and
14 as a consequence, they can't redesign the Ranitidine molecule.
15 Even manufacturers can't do that without the FDA's special
16 permission or assistance. They also can't change the label.
17 So, we agree that they can't comply with either of those sets
18 of state's duties.

19 That actually resurrects a topic that your Honor was
20 asking me about during the Q and A that I want to revisit,
21 which is, if you can't comply with all of the state
22 responsibilities that are imposed on you, does preemption
23 nevertheless prevent you from complying with the ones that you
24 can meet under both state and Federal law?

25 And you may recall that we were talking about

1 expiration dates in that context where we said the generics
2 could change the expiration date, but they couldn't necessarily
3 redesign the Ranitidine molecule, can that theory proceed?

4 This applies with equal force to the distributors and
5 the retailers where we concede they can't comply with any state
6 duties that would be imposed on them in order to change the
7 molecule or change the label, but they can still comply with
8 other duties. I pointed your Honor to cases like Bates and
9 Mink that stand for that proposition.

10 I wanted to frame it in slightly a different way to
11 maybe get to the same conclusion because I think this is maybe
12 a useful frame of reference to guide this discussion. Let's
13 take ourselves completely out of the preemption context. Let's
14 imagine that Federal law didn't exist with respect to
15 prescription drugs or over-the-counter drugs, or the FDA hadn't
16 implemented the regulations that we are going to be talking
17 about and have been talking about during today's discussion.

18 Just starting from basic first principles, a Plaintiff
19 is clearly master of her own complaint. If Ranitidine were
20 being sold on the exact same facts that we allege, she would
21 have a lot of different choices that she could pursue under
22 state law.

23 She could plead an expiration date theory against the
24 generic manufacturers. She could plead a negligence theory
25 against the distributors and retailers. She could plead a

1 design defect theory against all of the different Defendants
2 and say that they should have redesigned the molecule, and if
3 there are no Federal requirements that make it impossible to
4 comply with the state duties, all of those theories could
5 proceed.

6 But similarly, imagine a Plaintiff who just decided to
7 pursue an expiration date theory, or just decided to pursue a
8 negligence theory against the distributors and retailers. We
9 might scratch our heads and say, that is not customary, usually
10 the Plaintiffs don't choose to rein in their claims, they try
11 and bring everything that they can. But you would never throw
12 that out on a 12(b)(6) and say, well, you only brought the
13 expiration date theory, so the fact that you didn't bring the
14 redesign theory means you're of court. No, of course not.

15 The normal state substantive principles and the fact
16 that a Plaintiff is master of her own complaint would control
17 there. Her choice to pursue a narrower theory is not a shield
18 for the Defendants from liability. Preemption doesn't operate
19 that differently from that sort of stylized hypothetical. The
20 only difference is, under Federal law, the Plaintiff doesn't
21 have full flexibility.

22 If it is impossible to simultaneously comply with
23 state and Federal responsibilities some theories are foreclosed
24 to the Plaintiff, but others are not, and those theories remain
25 available to her to state a well-pleaded claim.

1 That is the situation that we have here with respect
2 to the distributors and retailers, as well as the other
3 categories of Defendants. We freely concede that they can't
4 redesign the molecule. We freely concede they have no ability
5 to change the label. That doesn't do anything to undermine the
6 other theories that we plead against them.

7 And it is true, in our original complaint we pled
8 all theories available under state law because we don't have an
9 obligation to anticipate an affirmative defense. They are the
10 ones who have to raise all of the Federal regulations and
11 statutory provisions that make it impossible to do certain
12 things under state law, and we agree that they have done
13 that successfully with respect to some of the things that we
14 plead in the complaint.

15 So, that is fine, those theories aren't available to
16 us any more based on the concession I just made as to certain
17 Defendants, but the remaining theories remain good, and we
18 can't be faulted for pleading all of the things available to us
19 under state law without knowing in advance which specific
20 affirmative defenses and arguments that they were going to
21 make.

22 They have that burden and they have satisfied it. We
23 are willing to agree with them that they satisfied it with
24 respect to certain theories, but the remainder of our theories
25 remain untouched.

1 Let me turn, your Honor, to the absolute versus strict
2 liability distinction which was left available in Bartlett. I
3 think we are a little bit of ships passing in the night on this
4 score, and I would just remind the Court of the teaching of
5 Bates, state duties, state requirements are not required to use
6 the same language or phraseology as Federal law.

7 We think that all of these causes of action against
8 the retailers and the distributors sound in strict liability.
9 So, my friend is not quite correct when she says that we gave
10 those up and we are only pursuing "absolute liability" claims.

11 There is no such thing under state law so far as we
12 know as a cause of action titled absolute liability, but under
13 strict liability principles, the Supreme Court in Bartlett was
14 leaving available an absolute liability regime and that is what
15 state law imposes on retailers and distributors under strict
16 liability theories as opposed to manufacturers.

17 The key insight to see here, your Honor, is that under
18 strict liability law that has existed for 50, 60, 70 years in
19 most states, the regime against manufacturers and the duties
20 imposed on manufacturers are different. Everybody recognizes
21 that manufacturers are the ones responsible for the labels and
22 the design of their products. Nobody puts those
23 responsibilities or duties on retailers and distributors.

24 And to once again remove us from the preemption
25 context to just a more commonplace example to put this into

1 focus, let me offer the following hypothetical.

2 Imagine that your Honor wanted to buy a light bulb, so
3 you went to Home Depot, you found a General Electric light bulb
4 that you like, you took it home. It came in the exact same
5 packaging that General Electric gave it to Home Depot in, there
6 was no alteration by Home Depot. You read the instructions,
7 you looked at the label, you screwed it into your lamp, you
8 flipped the switch, electricity flowed, and it exploded and
9 caused you injury, unfortunately. This is, of course, only a
10 hypothetical.

11 Under the law of almost every state, strict liability,
12 there is no doubt that you can sue Home Depot for your injury.
13 Why is that? It's not because state law imposes a duty on Home
14 Depot to redesign light bulbs delivered by General Electric.
15 Nobody thinks that.

16 It's not because Home Depot needs to have a team of
17 scientists on staff to review the label and make sure that
18 General Electric did a good job alerting you to all of the
19 risks associated with their product. Nobody thinks that
20 either.

21 The reason that Home Depot is liable, quite simply,
22 holding on the logic of luminaries such as Justice Traynor, is
23 that society has made a policy choice. We want downstream
24 providers like retailers and distributors, even though they
25 weren't at fault, even though they did nothing wrong, to pay to

1 protect hapless consumers from the vagaries of chance.

2 That is why strict liability as to retailers and
3 distributors is more like the absolute liability regime that
4 the Supreme Court was referencing in Bartlett. It is liability
5 without fault because we recognize that the retailers didn't
6 necessarily do anything wrong, but they nonetheless have to
7 pay to serve important public policy reasons.

8 Your Honor, I think the retailers and the distributors
9 in other contexts are already familiar with this. They make
10 the same arguments themselves. As Ms. Goldenberg said
11 yesterday, states like Minnesota, and others like Texas, have
12 passed, at the retailers' behest, so-called innocent seller
13 statutes. We talk about that in our second round of Motion to
14 Dismiss debriefing.

15 There are important exceptions that are relevant, but
16 for purposes of the preemption discussion, it is relevant to
17 note that they characterize themselves as innocent sellers, as
18 those who didn't breach any duties. They have persuaded state
19 legislatures in some states to agree with them.

20 I admit we all have a strong intuition that if you
21 haven't done anything wrong, maybe you shouldn't be made to
22 pay. The states, as sovereigns in an Erie analysis, have every
23 right to listen to their arguments and to embrace those public
24 policy principles, but the states who have chosen not to enact
25 those innocent seller statutes, they have the same right to

1 adhere to the more ancient principles that say even though they
2 have done nothing wrong, they should have to pay. That sure
3 sounds like absolute liability to me, your Honor.

4 Innocence means you are not at fault and you haven't
5 breached any duty, but conscripting the retailers and
6 distributors into the role of an insurance provider is
7 something we have been doing since, like I said, 50, 60, 70
8 years ago. It is a perfectly legitimate practice, and
9 preemption has nothing to say about it.

10 There is no duty under Federal law that they can point
11 to that says the public policy choices of the states that
12 adhere to the traditional rules of strict liability need to be
13 cast aside.

14 The final point that I want to address is the one my
15 friend concluded with, which is the Drug Supply Chain Security
16 Act, and once again, your Honor, let's start with what we agree
17 on.

18 We both seem to agree that no Court has ever construed
19 this provision, and so as a consequence, this Court has to
20 return to first principles and the canons of statutory
21 interpretation. As the Supreme Court and the Eleventh Circuit
22 have said multiple times, the first canon is the statutory
23 text.

24 Where the statutory text is plain, the sole function
25 of the Courts, at least where the disposition required by that

1 text is not absurd, is to enforce the statute according to its
2 terms.

3 We think that this entire regime comes down to the
4 word "tracing". Contrary to what my friend said, tracing is
5 not a defined term in the statute. The T in tracing in the
6 express preemption clause is not capitalized and so the word
7 gets its ordinary meaning.

8 Before turning to that, I just want to make sure that
9 I read the provision to the Court in full, because I think that
10 my friend omitted some key language that is important.

11 The statute's express preemption clause is 21 U.S.C.
12 Section 360eee-4. It says, "Beginning on November 7, 2013, no
13 state or political subdivision of a state may establish or
14 continue in effect any requirements for tracing products
15 through the distribution system."

16 There is then a parenthetical, including any
17 requirements with respect to statements and distribution
18 history, transaction history, it goes on and on, and then it
19 says, "or recordkeeping relating to such systems."

20 The "relating to such systems" language is crucial.
21 It means that the entire parenthetical is modifying the tracing
22 products through the distribution system language. So, once
23 again tracing is the crucial word that we need to define not
24 based on a statutory definition, but the plain and ordinary
25 meaning, your Honor.

1 How is trace defined? Well, Miriam Webster defines
2 trace as a verb, to follow the footprints, track or trail of.
3 The American Heritage Dictionary defines it as to locate or
4 ascertain the origin of. Roget's Thesaurus gives synonyms for
5 trace: Birddog, chase, follow, track, and hound.

6 None of our claims against the distributors or
7 retailers hinge on how they tracked Ranitidine through the
8 distribution system. We are willing to stipulate that they
9 followed the footprints of the Ranitidine containing products
10 perfectly. They knew which manufacturer it came from, when it
11 arrived at the distributor, where the distributor took it, when
12 it was dropped off, and when the pharmacist dispensed it to a
13 particular patient.

14 We will stipulate that they did all of that without a
15 breach of any state responsibilities.

16 None of our arguments hinge on a breach of those sorts
17 of duties. This is a very narrow express preemption clause,
18 and as my friend pointed out, there is a saving clause, and the
19 saving clause makes it even clearer that the statute is only
20 talking about tracing. Once again, tracing doesn't have a
21 capitalized T in the saving clause. It is based on the
22 ordinary meaning of that word that the Court should approach
23 the statutory interpretation question.

24 Thank you, your Honor.

25 *THE COURT:* Okay, thank you.

1 Did the Defendants want to come back on for any kind
2 of a rebuttal?

3 *MS. KAPKE:* Yes, your Honor, I would like to first
4 briefly address Mr. Keller's argument regarding our reply brief
5 on misbranding.

6 The retailers and pharmacy Defendants primarily defer
7 to the arguments ably made by the generics counsel and
8 forthcoming by the brand counsel.

9 But we did offer in reply an example of why
10 Plaintiffs' misbranding of parallel claim argument makes little
11 sense when applied to the retailers and pharmacies.

12 It is true that Section 333's good faith exception
13 only relates to criminal liability, but what that provision
14 does is demonstrate that Congress recognizes the difference
15 between manufacturers who have some control over the design and
16 labeling of a product and downstream Defendants who do not.

17 When a pharmacy dispensed Ranitidine as manufactured
18 by an FDA approved manufacturer, it was engaged in an act
19 that FDA specifically allowed. So, the misbranding argument
20 doesn't make sense to us as applied to the downstream
21 Defendants. That was in response to Mr. Keller's argument to
22 the distributors.

23 In response to our Mensing, Bartlett claim, Mr.
24 Keller explained that the retailers and pharmacies could comply
25 with other duties, but he never explained what duty that the

1 retailers and pharmacies violated other than to stop selling or
2 dispensing Ranitidine, and Bartlett squarely forecloses the
3 stop selling theory.

4 On the absolute liability versus strict liability
5 idea, it is interesting to me because he said in earlier
6 arguments that strict liability is based on a duty not to sell
7 a defective product. That is a duty in and of itself, and it
8 is different than absolute liability because there is an aspect
9 of defectiveness to the claim. Plaintiffs cannot prevail on
10 their claim unless they prove that Ranitidine is defective.

11 Now, they have alleged that Ranitidine is defective,
12 and we will accept that for purposes of a 12(b)(6) motion, but
13 absolute liability is very different. Absolute liability is
14 worker's compensation or a vaccine act claim where all you have
15 to do is prove causation, you don't have to prove some sort of
16 defect.

17 The duty here is a duty not to sell a defective
18 product. Plaintiffs want to focus on a duty to compensate
19 versus a duty not to sell. There is no duty to compensate
20 injured parties under a strict liability theory. A strict
21 liability theory is what Plaintiffs are relying on in this
22 discussion, supposedly, according to my friend, Mr. Keller,
23 but, really what they are doing is a duty not to sell, and that
24 is where Bartlett squarely forecloses their theory.

25 Finally, I will turn back to the Drug Security Act and

1 in claiming that this is a narrow preemption clause, Plaintiffs
2 for the first time make an argument that the last part of the
3 parenthetical modifies the entire part, but I'm reading it
4 right now, and I just don't understand this argument.

5 It says, "any requirements for tracing products
6 through the distribution system, including any requirements
7 with respect to transaction statements." The transaction
8 statement is the centerpiece of this preemption argument, and
9 Plaintiffs have no response to it.

10 What my friend did not address, but he did in
11 opposition, was retroactivity, so I want to spend a few minutes
12 on retroactivity because there are two fundamental reasons why
13 Plaintiffs' claims about retroactivity are wrong and why it
14 makes sense for us to address now in rebuttal.

15 First, Plaintiffs don't sit *Landgraf* in its proper
16 context. The *Landgraf* Court confirmed the principle in *Bradley*
17 versus *School Board* at 416 U.S. 696. The Court should apply
18 the law in effect at the time the Court renders its decision.
19 There is no issue of retroactivity when a Court simply applies
20 the law as it applies now to claims that vested after
21 the announcement of the Drug Supply Chain Security Act.

22 Indeed, to quote *Landgraf* directly, "A statute does
23 not operate retrospectively merely because it is applied in a
24 case arising from conduct antedating the statute's enactment."
25 That is at *PIN* cite site 269416 U.S., at 269.

1 Landgraf dealt with whether a new law can pose new
2 penalties for prior conduct without an expressed statement that
3 Congress intended to do so.

4 There is a significant difference between ensuring
5 that punitive measures are imposed only when Congress spoke
6 clearly and prospectively limiting future claims that have not
7 yet arisen, which is what Congress did in this particular
8 preemption provision.

9 Second, Landgraf makes clear that you only apply the
10 presumption against retroactivity when the statute is not
11 clear. Here, the statute is clear. Congress said that states
12 may not continue in effect any state law requirements, continue
13 in effect. In *Re: Fontem*, cited in the distributors' reply
14 brief and at 2017 WestLaw 10402988, makes clear that the words
15 continue in effect "evinces an intention" to bar any
16 conflicting state requirements that may have existed before the
17 preemption clause came into effect.

18 Plaintiffs' response to the words "continue in effect"
19 is to attempt to relitigate the idea of whether state-law
20 common law duties are, in fact, requirements, citing language
21 from *Bates* that jury verdicts are not requirements when they
22 merely motivate an optional decision.

23 But Plaintiffs' omit several important points. First,
24 the *Bates* Court agreed that common law duties are state law
25 requirements in a different part of its opinion.

1 Second, Bartlett discussed this portion of Bates in
2 depth explaining that Bates found the design defect claim not
3 preempted because the claim in question in Bates did not fall
4 within the scope of the express preemption provision of the
5 Federal Insecticide, Fungicide and Rodenticide Act.

6 Common law duties are requirements under consistent
7 and repeated Supreme Court precedent. The only specific law
8 cited in the briefs on the effect of the words "continue in
9 effect" respond to In Re: Fontem and Colgate versus Juul Labs,
10 both of which found that the words "continue in effect" show
11 clear Congressional intent to apply preemption to all claims.

12 To quote Fontem, "If this Court concluded that the
13 final rule does not preempt Plaintiffs' claims arising prior to
14 the date of the enactment of the final rule in Fontem then it
15 would continue to apply conflicting state restrictive
16 requirements, however, the statutory language expressly
17 prohibits this," end quote.

18 Thank you, your Honor. We are happy to answer any
19 questions.

20 *THE COURT:* Okay, thank you. So we can have all of
21 the attorneys for both motions 1583 and 1584 to come on the
22 screen since I said I was going to defer any questions from
23 1583 until after I heard 1584. You can decide who among
24 yourselves will want to answer the questions as I pose them.

25 Okay. Let me just begin with the same question I

1 asked earlier this morning. For the preemption motions that
2 were filed by the Defendants, as to the two motions we are
3 discussing, 1583 and 1584, the motions state that they are a
4 Rule 12 motion.

5 I just want to confirm that each motion is a 12(b)(6)
6 motion based on affirmative defenses.

7 *MS. JOHNSTON:* Your Honor, Sarah Johnston for the
8 retailer and pharmacy Defendants. That is correct.

9 *MR. KAPLAN:* Your Honor, Andrew Kaplan for the
10 distributor Defendants. That is correct.

11 *THE COURT:* Okay. With respect to -- let's see. Also
12 a similar question, and I know that Mr. Keller for the
13 Plaintiffs already answered it when I posed it earlier this
14 morning.

15 Do Defendants agree that impossibility preemption
16 means that state law imposes a duty or obligation to do
17 something, but Federal law prevents you from doing it?

18 *MS. JOHNSTON:* Your Honor, Sarah Johnston for the
19 retailers. Is that a question for the Defendants?

20 *THE COURT:* Yes.

21 *MS. JOHNSTON:* We agree.

22 *MR. KAPLAN:* Your Honor, Andrew Kaplan for the
23 distributors. I would agree except for the issue of stopping
24 selling, which I think falls outside that rubric because that
25 is an action that you could take, but it is still preempted.

1 *THE COURT:* Okay.

2 I want to follow up first with a couple of things that
3 Mr. Keller said before I get into more particular questions
4 that I have.

5 Going back to your presentation, Mr. Keller, a moment
6 ago, I just want to confirm, did I hear you correctly when you
7 said that you are aware of no state that has an absolute
8 liability cause of action against the retailers and the
9 distributors?

10 *MR. KELLER:* Ashley Keller for the Plaintiffs, your
11 Honor. Yes. I want to make sure that I am clear, though, we
12 are aware of no state that calls it an absolute liability cause
13 of action. They call it strict liability.

14 *THE COURT:* And you have referenced several times that
15 retailers and distributors don't necessarily do something
16 wrong, but isn't the proper way to frame it under strict
17 liability that what they did wrong was to sell a defective
18 product? Which I think Ms. Kapke was touching on.

19 *MR. KELLER:* Ashley Keller again for the Plaintiffs,
20 your Honor. No, I don't think that that's the right way to
21 frame it. I think that is the right way to frame it for a
22 manufacturer.

23 With respect to a retailer, they are not in any
24 position to know if the product is defective, that is
25 particularly so for prescription drugs. Unlike a manufacturer

1 who, acting even above a negligent standard of care could have
2 certainly caught that their product was defective, there is
3 nothing a retailer or distributor could do to make that same
4 sort of catch. So, there is no duty that they breached that
5 they could have complied with.

6 *THE COURT:* Okay. As to the Plaintiffs, as of today,
7 could a retailer or a distributor sell Zantac? In other words,
8 does the voluntary recall issued by the FDA mean that
9 a retailer or a distributor is compelled by Federal law not to
10 sell Zantac?

11 *MR. KELLER:* Is that for the Plaintiffs, your Honor?

12 *THE COURT:* Yes.

13 *MR. KELLER:* Ashley Keller for the Plaintiffs. Your
14 Honor, the FDA's direction that the retailers, distributors,
15 and manufacturers should pull Zantac from the market was a
16 voluntary recall, so that action by itself wouldn't make it
17 unlawful for them to start selling again.

18 It would nonetheless be unlawful for them to start
19 selling again because Zantac or Ranitidine is misbranded. It
20 meets the definition of a misbranded drug.

21 The FDA in its amicus brief in Bartlett noted that
22 even though the misbranding statute is satisfied, the FDA will
23 often go through the route of a voluntary recall instead of a
24 required recall because there are due process considerations
25 with telling an NDA or an ANDA holder that they have to stop

1 selling, and so the FDA typically prefers to say you better
2 pull this from the market or we'll do something more formal,
3 and uniformly the manufacturers, retailers, and distributors
4 agree with that.

5 Technically, the recall as it stands right now is
6 voluntary, so that by itself doesn't require them to stop
7 selling. It's the fact that they meet the statutory definition
8 of misbranding that requires them to stop selling.

9 *THE COURT:* Okay. To the Plaintiffs as well, Mr.
10 Keller, following up on the topic of absolute liability. There
11 is much discussion in your briefing and here today over whether
12 the retailers and the distributors are absolutely liable for
13 the sale of drugs.

14 Assume for the moment that the quintessential absolute
15 liability cause of action, and again this was also referenced
16 today, is something akin to worker's compensation. We know
17 that in worker's compensation one does not need to prove that
18 the employer actually did something wrong, the injured employee
19 is entitled to payment even if the employer was not negligent.
20 That is *Holliday versus Personal Products Company*, 939 F.Supp.
21 402, at 404, Eastern District of Pennsylvania, 1996.

22 I have two questions. First, if you were to try a
23 strict products liability case against a retailer, would you
24 agree you would have to prove that the product was defective
25 regardless of whatever state you were in?

1 And second, are you aware of any state that would
2 permit you to try a strict products liability case over Zantac,
3 but where you would not be required to show any evidence that
4 something was wrong with Zantac or Zantac's label?

5 *MR. KELLER:* The answer to question one is yes. The
6 answer to question two is no. Ashley Keller again for the
7 Plaintiffs. I am sorry, Ms. Stipes.

8 *THE COURT:* Okay, thank you. Another question for Mr.
9 Keller for the Plaintiffs, and this relates to the Drug Supply
10 Chain Security Act. And there has been much discussion of that
11 as well today in your presentations, so you may have answered
12 it in part, but let me pose the question nevertheless.

13 The Drug Supply Chain Security Act lists the criteria
14 that must be present to accept a shipment of drugs. For
15 example, and this has been referenced, you must refuse to
16 accept a shipment of drugs if the shipment is missing certain
17 information about the drugs. That's 21 U.S.C. Section 360eee,
18 subsection 26 to 27.

19 The list of criteria, however, does not include any
20 requirement to refuse to accept a shipment of drugs if you have
21 not independently verified that the drugs are pure or otherwise
22 do not have a defect.

23 The Drug Supply Chain Security Act expressly preempts
24 any state law that would seek to impose additional requirements
25 in a supply chain that pertain to investigation. That is at 21

1 U.S.C. Section 360eee-4(a).

2 Is it Plaintiffs' position that a distributor should
3 have refused to accept a shipment of Zantac from the
4 manufacturers?

5 Similarly, is it the Plaintiffs' position that the
6 retailers should have refused to accept a shipment of Zantac
7 from the distributors? If so, why should they have refused?
8 In other words, what would be the basis for the refusal?

9 MR. KELLER: Ashley Keller for the Plaintiffs. Yes,
10 it is our position that they should have refused to accept
11 shipments of Ranitidine containing products regardless of what
12 information they had on these tracing statements because of the
13 misbranding provisions of Federal law.

14 The provision that you referred to, 360eee-4, as well
15 as the other provision, does nothing to alter the misbranding
16 statute and the duties created under it. The misbranding
17 statute is a strict liability offense that imposes an absolute
18 duty without any knowledge requirement, without any good faith
19 dispensation to stop selling a misbranded drug or to not
20 receive it in interstate commerce.

21 And once again, the proof for that, outside of the
22 criminal context where there is a good faith exception, is the
23 United States can seek an injunction and seize all of the
24 Zantac that a distributor has received, and they can't point to
25 any statement they have in their possession saying we didn't

1 know it was misbranded to avoid that injunction and that civil
2 remedy. It's absolute, they must stop selling or receiving
3 that product in interstate commerce.

4 *THE COURT:* Another question for the Plaintiffs, Mr.
5 Keller.

6 Let's say that state law would require a retailer to
7 store Zantac at 50 degrees Fahrenheit. Let's also say,
8 however, that FDA approved storage conditions contain a range
9 of temperatures for storage, but the range is above 50 degrees.
10 For example, suppose the range of FDA approved storage
11 conditions is 55 degrees to 80 degrees.

12 Would you agree that impossibility preemption would
13 apply to the state law, that is, you can't simultaneously store
14 a drug at two different temperatures?

15 *MR. KELLER:* Ashley Keller for the Plaintiffs. Under
16 your hypothetical, if the state law were so specific as to say
17 you must store it at 50 and the Federal law said you must store
18 it between 55 and whatever else, higher temperatures, yes, that
19 50-degree example would be preempted because it is impossible
20 to square with the range created by Federal law.

21 We, of course, not to fight your hypothetical, don't
22 think that that's our case. Our negligence allegations against
23 the retailers and the distributors are that they didn't comply
24 with the Federally mandated temperature ranges, and as a
25 consequence, allowed NDMA to form in Ranitidine containing

1 products.

2 But under the example you gave, yes, there would be
3 preemption.

4 *THE COURT:* Can you point the Court to a case cited in
5 your briefing where a Plaintiff was found to have stated a
6 claim of any sort where the allegation was that the Defendant
7 had stored drugs in accordance with FDA approved storage
8 conditions, and should be found liable for such storage?

9 And relatedly, can you direct my attention to where,
10 if it exists in your briefing or complaint, the Plaintiffs
11 contend that an entity did not store Zantac pursuant to FDA
12 approved storage conditions?

13 *MR. KELLER:* Ashley Keller for the Plaintiffs. I
14 don't believe that we point to a case, your Honor, that
15 addresses your first situation, but it's worth noting that the
16 situation here is fairly unique.

17 The cancer causing compound, NDMA, forms precisely
18 because of the storage conditions of the drug, at least in
19 part, and so there probably aren't a lot of examples of a
20 molecule that inherently contains within it a cancer causing
21 compound that gets released when it is stored at particular
22 temperature ranges.

23 So, the lack of a case, I don't think is fatal to our
24 theory. Just basic preemption principles support our analysis,
25 and I don't believe there is any case on the other side of the

1 ledger either that the other side has cited, recognizing again
2 that it is their burden to establish an affirmative defense. I
3 don't think they point to any temperature changes where state
4 law says, to change your hypothetical a little bit, store this
5 at 55 degrees, Federal law says store it between 55 and 80, and
6 that is found preemptive. So, based on first principles, we
7 are in good shape.

8 I would point the Court to the master personal injury
9 complaint for your second question, to paragraph 407 that talks
10 about the fact that there was improper storage and transport
11 conditions. I think those factual allegations have to be
12 accepted as true.

13 And as I noted to your Honor earlier, I think that
14 these allegations are more than plausible when you look at the
15 FDA batch testing that shows, again, the different amounts of
16 NDMA forming in Ranitidine containing products.

17 A plausible inference that should be drawn in our
18 favor here, since we don't have full discovery yet, is that a
19 significant part of that dispersion was caused by the storage
20 and transport (inaudible) that were undertaken by these
21 Defendants.

22 *MR. KAPLAN:* Your Honor, this is Andrew Kaplan. May I
23 respond to that point about the allegations in the complaint?

24 *THE COURT:* Yes. I wanted to confirm with Mr.
25 Keller, it is paragraph 407 is what you are relying upon of the

1 MPIC?

2 MR. KELLER: Among others. Paragraph 409, paragraph
3 457 would also be relevant. But 407 is where we talk about
4 testing by the FDA and we say that it resulted in extremely
5 high levels of NDMA because of improper storage conditions, and
6 that is backed up by some other paragraphs like the ones I just
7 mentioned.

8 THE COURT: So, are you saying implicit, for example,
9 in 407 is an allegation that the entity did not store -- or
10 entities did not store Zantac pursuant to FDA approved storage
11 conditions?

12 MR. KELLER: Correct, your Honor, I think that is a
13 plausible inference, again, just given the different levels of
14 NDMA we have seen in the different batches. We don't know for
15 sure what temperatures they stored this at because we don't
16 have access to that full discovery yet.

17 So, we have to plead based on the facts we can glean
18 from the public record. We have the FDA's public record of how
19 much NDMA was formed in Ranitidine. We think it is plausible
20 at this stage that a good portion of that, especially because
21 there were differences between different batches, is the
22 storage and transport conditions.

23 THE COURT: Mr. Kaplan, did you want to say something?

24 MR. KAPLAN: Yes, Andrew Kaplan on behalf of the
25 distributor Defendants.

1 I would like to respond to the suggestion that the
2 complaint pleads that the distributors have violated the
3 shipping and storage requirements on the labeling.

4 First of all, we don't see that clearly in this
5 lengthy complaint, and Mr. Keller has pointed to paragraph 407
6 earlier today and again now. Instead, they allege a contrary
7 claim that the product should have been stored or shipped at
8 cool temperatures that are outside the room temperature storage
9 ranges on the labels. And the claim that Plaintiffs have
10 actually pleaded is preempted, especially for distributors who
11 can't change the label or required storage conditions.

12 Mr. Keller, in pointing to paragraph 407 of the master
13 personal injury complaint which states "testing conducted by
14 the FDA confirms that the improper storage of Ranitidine has
15 resulted in extremely high levels of NDMA."

16 And earlier Mr. Keller referenced in the footnote 120
17 to that paragraph where they cite to an FDA letter to Emory
18 Pharmaceuticals that they contend supports the suggestion that
19 this is a -- plays a plausible allegation of deviation from the
20 required temperature storage and shipping.

21 First, we don't read this as a direct allegation that
22 any specific Defendant, or even a group of Defendants, actually
23 did violate label required storage and shipping requirements,
24 and even if one were to stretch in an interpretation of this
25 one sentence that is in the factual background section, the

1 letter it cites as support does not actually provide that
2 support.

3 The Emory letter only says that "elevated temperatures
4 can lead to the presence of NDMA in the drug product." In
5 fact, the letter went on to say that a root cause analysis was
6 still ongoing.

7 Bottom line is, they have no specific allegation
8 against any specific distributor that they did anything wrong,
9 it is all speculation. Plaintiff must have a plausible basis
10 for a claim before they file their complaint, not wait until
11 discovery to hope they turn up a good faith basis for the
12 claim.

13 They can't plausibly allege that the distributors
14 violated shipping and storage requirements. Mr. Keller
15 contends that the variation of NDMA in samples tested make it
16 plausible that the distributors didn't handle the product
17 correctly, but Plaintiffs acknowledge that under label required
18 storage and shipping temperatures there is a range of allowable
19 temperatures.

20 Any variation in tested batches, to the extent that it
21 is even related to temperature, which is conjecture, could
22 differ based on the permissible temperature ranges, and beyond
23 that, the storage and shipping requirements specifically allow
24 excursions from the standard temperature range and, indeed,
25 Plaintiffs argue for cool storage that would presumably deviate

1 from the standard temperature range, and any variations in
2 tested batches could just as easily result from the normal
3 handling with different permissible excursions.

4 Under *Twombly* and *Iqbal*, that a theory is merely
5 possible according to factual allegations is not sufficient to
6 make it plausible. So, to the extent that the Court credits
7 Plaintiffs' current argument that this claim is in the
8 complaint, it should be dismissed because as not plausible.

9 To the extent the Court agrees that it is not in the
10 complaint, as we see, Plaintiff has not offered a Rule 11 good
11 faith basis to replead to add such an allegation.

12 *THE COURT:* I have a followup question for Mr. Keller
13 just in this topic.

14 What are the improper storage conditions that are
15 being alleged here? If you don't know what the temperatures
16 are, which I am understanding that you don't because you
17 haven't conducted discovery, how do you know that they don't
18 comply with FDA storage conditions?

19 *MR. KELLER:* Ashley Keller for the Plaintiffs.

20 I think that this whole discussion shows that we have
21 veered, appropriately, from preemption to the 12(b)(6)
22 standard, and we think we do satisfy *Iqbal* and *Twombly* which,
23 of course, says you don't credit mere conclusory statements or
24 threadbare recitals of the elements of the cause of action, but
25 you do credit well-pleaded factual allegations even if they are

1 short statements of fact.

2 We have all throughout the complaint -- I pointed to
3 paragraph 407 as an example, but it is just one example --
4 statements saying that Ranitidine breaks down at higher
5 temperatures into NDMA. This is not just mere conjecture. It
6 might be proven true at summary judgment, to Mr. Kaplan's
7 point, but it is more than plausible based on the studies that
8 have already been conducted when exposing Ranitidine to much
9 higher temperatures that a much greater amount of NDMA is
10 formed.

11 So, when you take that, coupled with the fact that
12 there is dispersion in the batches and FDA has noticed
13 different Ranitidine containing products with significantly
14 different levels of NDMA, we think it is quite plausible that
15 the reason for that is the storage and transport conditions.

16 I agree I can't say, under Rule 11, that this
17 particular distributor took that particular batch and stored
18 it, even with the excursions, outside of the temperature range
19 contained on the label, in violation of both state and Federal
20 law. I don't have that level of specificity right now, but
21 I would respectfully posit that Rule 12(b)(6) doesn't require
22 that of a Plaintiff to get past this phase of the proceedings.

23 We have pled enough to get discovery. If it turns out
24 on summary judgment, after taking depositions and getting
25 documents, they did everything right, everything was within the

1 temperature ranges contained on the label, they can get summary
2 judgment on this question.

3 We agree that staying within the ranges of the label
4 is required by Federal law, so we are willing to stipulate to
5 that proposition. We do not agree and we don't think the
6 complaint is faulty for saying that they didn't comply with
7 that.

8 MS. JOHNSTON: Your Honor, if I may I briefly respond
9 to that?

10 THE COURT: Yes.

11 MS. JOHNSTON: Sarah Johnston for the retailer
12 Defendants. I would just add that in this discussion of what
13 the complaint actually says and the Plaintiffs' opposition
14 actually says, one paragraph we are skipping over is paragraph
15 408, which is the only paragraph in the complaint that
16 identifies what the obligation is. The obligation, according
17 to Plaintiff, is that we were obligated to ensure cool storage
18 and transport.

19 That is very different than room temperature and it is
20 very different than Mr. Keller's recollection of the complaint
21 as he said. Paragraph 408 is repeated verbatim in Plaintiffs'
22 opposition to our Motions to Dismiss, and this is an allegation
23 that, as we have looked through this complaint, doesn't appear
24 anywhere, nothing that says that we went outside of the labeled
25 conditions.

1 And we have brought a Motion to Dismiss based on the
2 complaint before us, and this is not the complaint before us.

3 *MR. KELLER:* Your Honor, can I respond to that?

4 *THE COURT:* You may.

5 *MR. KELLER:* Thank you, your Honor. Ashley Keller for
6 the Plaintiffs. This once again returns to a concept that I
7 understand why we have kept coming back to, which is that state
8 law can often require a broader set of responsibilities than
9 Federal law does, but there is only preemption to the extent of
10 the difference.

11 Yes, we think that state law could have required them
12 to store, if you were only looking to state law, at even colder
13 temperatures than the ones on the label, but those colder
14 temperatures, if you went below the bottom of the range, would
15 be preempted.

16 That doesn't absolve them from responsibility for
17 sticking with the temperature ranges contained on the label.
18 To the extent that they violated that responsibility, there is
19 no preemption.

20 Once again, we pleaded these complaints before seeing
21 their affirmative defense. We don't have to anticipate the
22 affirmative defenses that they are going to make to have a
23 well-pleaded complaint under Rule 8. Once they file their
24 oppositions and try to dismiss on the basis of preemption, of
25 course we react to that and we are willing to stipulate, as

1 officers of the Court with the duty of candor, that they have
2 made some preemption arguments that have teeth, and that's
3 fine, but we are still allowed to proceed on the narrower
4 theories that are still actionable under state law.

5 *THE COURT:* Okay. Thank you. For the Plaintiffs, Mr.
6 Keller, you argue that the Drug Supply Chain Security Act is
7 only about tracing a product through the drug supply chain, and
8 since you argue that the Plaintiffs' claims have nothing to do
9 with product tracing, the act does not apply.

10 If your allegations supporting general negligence are
11 that, at some point, the drugs were overheated and therefore
12 produced NDMA, doesn't that involve tracing the product through
13 the supply chain?

14 In other words, if a retailer sold NDMA-laced Zantac
15 as a result of exposure to high temperatures, where did those
16 exposures to high temperatures occur, at the store? With one
17 of the distributors? At the factory waiting for pickup?

18 Wouldn't answering that question necessarily involve
19 tracing a product through the supply chain?

20 *MR. KELLER:* Thank you, your Honor, Ashley Keller for
21 the Plaintiffs. First a quick clarification and then directly
22 answering your question.

23 I don't think we said that the Drug Supply Chain
24 Security Act was exclusively about tracing. What I meant to
25 say, if I didn't say this correctly, is that the express

1 preemption clause is exclusively about tracing. Section
2 360eee-4, which is the express preemption clause, is about
3 tracing. There are indeed other provisions of the act, but
4 Congress only saw fit to expressly preempt things involving
5 tracing.

6 To go to your Honor's question, no is the answer. I
7 don't think that them leaving Ranitidine on a hot truck outside
8 of the variances that are allowed for a significant period of
9 time are about tracing. It is not about them breaching their
10 duty to know where the product is; it is about them breaching
11 their duty to store it at the ranges contained on the label.

12 They may have perfectly documented, in fact, I hope
13 they have perfectly documented exactly where that product is so
14 that we, as Plaintiffs, can trace it and get access to the
15 discovery. I hope they have all the paperwork that the act
16 requires of them so it will be easier for us to make the case
17 to you, as we plead plausibly now, that they actually stored
18 this outside of the temperature ranges.

19 But storing it outside of the temperature ranges isn't
20 tracing. Maybe identifying that they stored it outside of the
21 temperature ranges is tracing, but the two are not (inaudible).

22 *THE COURT:* For the Plaintiffs, Mr. Keller, are you
23 aware of any MDL wherein retailers or distributors were named
24 as defendants in a master complaint and a claim against those
25 defendants survived a Motion to Dismiss post Bartlett and post

1 Mensing MDLs?

2 *MR. KELLER:* I am not aware of one, your Honor, and I
3 am also not aware of one where evidence of misbranding is as
4 strong as it is here.

5 *THE COURT:* This is a question for the Defendants. If
6 all of the claims against the retailers and distributors are
7 preempted, the second round motions, the distributors' Rule 12
8 Motion to Dismiss on various group-specific grounds, and the
9 retailer and pharmacy Defendants' Rule 12 Motion to Dismiss on
10 state law grounds, do those motions become moot?

11 *MR. KAPLAN:* Your Honor, this is Andrew Kaplan for
12 distributor Defendants. If the Court accepts our arguments on
13 preemption, this would apply to all of the claims in the master
14 personal injury complaint and the consumer class complaint, and
15 therefore the remaining motion would be moot, yes.

16 *MS. JOHNSTON:* Sarah Johnston for the retailers. We
17 agree, your Honor.

18 *THE COURT:* Okay. All right. Thank you all so much,
19 I appreciate it. That concludes the discussion on 1583 and
20 1584, the questioning.

21 I would now ask that counsel come up for the last
22 motion to be heard today, which is 1580. Actually this would
23 just be Defendants coming up. This is Defendants' Rule 12
24 partial Motion to Dismiss Plaintiffs' three complaints as
25 preempted by Federal law and incorporated memorandum of law.

1 And as I understand it, there will be 18 minutes allotted to
2 the Defendants.

3 And so, if counsel could state their appearance for
4 the record, and let me know if you would like to divide your
5 time up; and if so, how.

6 *MS. EISENSTEIN:* Good afternoon, your Honor, this is
7 Ilana Eisenstein. I represent the Sanofi Defendants, and in
8 this motion we will be speaking on behalf of the branded
9 Defendant manufacturers. With me is my associate, Rachel
10 Horton, who will be introducing this motion.

11 If we could, we would like to divide it up, I believe
12 Ms. Horton will take approximately three minutes of time to
13 introduce the matter, and then I would like to leave three
14 minutes or so for rebuttal.

15 *THE COURT:* Dividing it up, 15 and three, and any kind
16 of a warning?

17 *MS. EISENSTEIN:* When there is three minutes left of
18 time, if you don't mind, and we can decide whether to proceed
19 or dig into the rebuttal time, that will be great. Thank you.

20 *THE COURT:* All right. You may proceed.

21 *MS. HORTON:* Good afternoon, your Honor. Can you see
22 and hear me?

23 *THE COURT:* I can see and hear you. Good afternoon.
24 Sorry, I can see and hear you, thank you. You may proceed.

25 *MS. HORTON:* Wonderful. I am Rachel Horton and I am

1 joined by my colleague Ilana Eisenstein. Ms. Eisenstein and I
2 will be arguing on behalf of the branded Defendants about why
3 Plaintiffs claims are preempted by Federal law. My
4 introduction will provide an overview of Ms. Eisenstein's
5 arguments.

6 Plaintiffs are correct that the preemption analysis
7 compares Federal and state requirements, however, Plaintiffs
8 misstate both. Plaintiffs claim that any unsafe aspect of a
9 medication violates the Federal misbranding statute. That is
10 incorrect. The source of Federal requirements is the NDA.

11 The Federal misbranding statute is only violated with
12 a departure from the FDA approved labeling or formulation.

13 In defending against these Motions to Dismiss
14 Plaintiffs ignore the gravamen of the complaints which allege
15 that Zantac is inherently unsafe, Zantac should have been
16 labeled differently, that Defendants should have made
17 statements other than what was in the label.

18 Plaintiffs fall back on narrow, isolated allegations
19 in their complaint. In doing so, Plaintiffs seek an order that
20 Defendants stop selling, which has been rejected by every Court
21 that has considered such a demand.

22 Having excised the preempted theories of liability,
23 the next step is for the Court to evaluate whether any viable
24 claims remain. Plaintiffs here cannot use their narrow
25 theories of liability to save the remainder of their claims

1 from preemption.

2 Next I will address express preemption and then
3 implied preemption. Plaintiffs in the MDL have brought 320
4 state law claims, either individually or on behalf of the
5 putative class, that seek economic damages or refunds for
6 over-the-counter Zantac, however, the Federal Food, Drug and
7 Cosmetic Act expressly preempts claims that seek a refund for
8 over-the-counter Zantac.

9 Section 379(r), subsection a, bars consumers from
10 filing state law claims for economic harms relating to
11 over-the-counter products that are different from, in addition
12 to, or otherwise not identical with the FDCA's requirements.
13 All three complaints allege that the FDA approved formulation
14 and label were not worth the purchase price. Such claims are
15 expressly preempted.

16 State and Federal Courts throughout the country have
17 so held because Plaintiffs merely base their claims on a
18 manufacturer's failure to change medication labeling,
19 packaging, or other branding which would sidestep Federal law.

20 Plaintiffs are incorrect that their claims are saved
21 by Section 379(r), subsection e's narrow personal injury
22 savings clause. Plaintiffs have not alleged any physical
23 injury or property damage. That means Plaintiffs have no
24 personal injury claims under Federal law, which is the standard
25 this Court should apply, or even under the law of the vast

1 majority of states.

2 Plaintiffs seek to bypass express preemption by
3 claiming that they are asserting a parallel claim based on a
4 purported violation of the Federal misbranding statute. That
5 argument fails because it is based on an internal
6 contradiction. No Court has found that the medication that
7 complies with its FDA approved labeling and formulation is
8 "misbranded". Such medications are by definition correctly
9 branded because the FDA has approved their label and
10 formulation.

11 As to implied preemption, Plaintiffs assert design
12 defect claims for both over-the-counter and prescription Zantac
13 in the personal injury and consumer class action complaints.

14 The heart of those 49 claims is that the branded
15 Defendants should have designed Zantac or Ranitidine
16 differently. Under the Supreme Court's precedent in Mensing,
17 such claims are impliedly granted. It was impossible for the
18 branded Defendants to comply with an alleged state duty to
19 redesign medication where FDA regulations prohibit a
20 manufacturer from unilaterally doing so.

21 Plaintiffs assert no viable response to the branded
22 Defendants' implied preemption argument. Instead, they say
23 their design defect claim merely states redundant failure to
24 warn and labeling claims. Thus, this Court should dismiss with
25 prejudice Plaintiffs' challenges to the design, formulation,

1 and chemical composition of Zantac.

2 Thank you.

3 *MS. EISENSTEIN:* Thank you, Ms. Horton. This is Ilana
4 Eisenstein.

5 Your Honor, we have heard the term "misbranding"
6 countless times today on the part of the Plaintiffs, and I am
7 sure your Honor is left wondering, how does this really play
8 into the preemption arguments that we are asserting here as a
9 basis to dismiss.

10 I want to clarify a few things to build on what
11 Ms. Horton argued about how express preemption works and how
12 implied preemption works and why this misbranding theory simply
13 is no defense to the motion that seeks preemption of broad
14 swaths of the Plaintiffs' consumer class action claims and the
15 design defect claim.

16 Let me start with the express preemption provision. I
17 think there is one thing that Plaintiffs and Defendants can
18 agree on. Mr. Keller states that the Federal preemption
19 inquiry with respect to the express preemption in particular
20 requires a comparison of the state requirements on the one hand
21 to the Federal requirements on the other to see if they are the
22 same, and state requirements are preempted to the extent they
23 differ from, or add to, or are not identical with the Federal
24 requirements, but here is where we depart.

25 The Plaintiffs try to use the staggering breadth of

1 their own allegations and a mistaken mischaracterization of
2 Federal misbranding law to obscure the preemption of really the
3 heart of their complaint, and in particular, their class action
4 complaint with respect to the consumer claims that seek a
5 refund for the price of Zantac.

6 This boils down in their brief to the claim that both
7 state and Federal law impose the same duty, do not sell a
8 dangerous drug. This simplistic view is a mischaracterization
9 of their own claims and it's a mischaracterization of
10 misbranding law.

11 Let me start with the Federal side. It is simply
12 incorrect that Section 352 makes it a crime to sell a product
13 that complies with the Federally approved label and
14 composition. It is departures from the approved label and
15 departures from the approved formulation and design, or
16 departures from Federal manufacturing standards that can give
17 rise to a misbranding violation.

18 Plaintiffs have not pointed to a single Court
19 regulatory action or other place where they can say that here
20 has been a misbranding allegation under these circumstances.

21 Instead, if you look at what is the source of Federal
22 requirements, the source of Federal requirements isn't the
23 misbranding statute, so the other problem with the Plaintiffs'
24 allegations is, they try to hinge the source of Federal
25 requirements on these generalized notions in the misbranding

1 statute, not the NDA itself.

2 You look at Court after Court when they have tried to
3 evaluate what are the Federal requirements to which we're
4 comparing the state requirements, they look to the NDA, and
5 that is true in the cases that involved OTC preemption, which
6 are fewer and farther between, but they include the Carter
7 case, the Mills case, the Canter case, all of which are cited
8 in our briefs.

9 It is also true in the much more robust arena of
10 the medical device amendments where, when Courts try to
11 evaluate in the medical device amendments what are the
12 Federal requirements at issue, they look to the premarket
13 approval, which is the equivalent for devices of an NDA. It is
14 the premarket approval, along with certain manufacturing
15 requirement, and perhaps storage and transportation
16 requirements, that form the Federal requirements to which state
17 requirements are compared.

18 So, the premise of Plaintiffs' claim that misbranding
19 is this catchall that sucks in any unsafe product is simply
20 untrue, and when stripped away from that premise and focused
21 instead on the true Federal requirements, I think it is clear
22 why the consumer class action claims are preempted.

23 Before I get to that, I do want to refute one thing
24 that I heard earlier today from Mr. Keller.

25 He stated on at least a couple of occasions that the

1 FDA regulatory action in this case, the voluntary recall by
2 manufacturers and then the FDA recall of Zantac, established in
3 some conclusive way either that Zantac is dangerous, or he even
4 stated early on in his argument that it is misbranded.

5 That is simply not the case. There is no finding by
6 the FDA of danger with respect to Zantac. There has been no
7 findings by the FDA at all other than a precautionary measure
8 to remove Zantac from the market in light of the allegations
9 that were made.

10 There are legions of cases that have held that a
11 recall doesn't create evidence of a violation of Federal law.
12 It is certainly not evidence of misbranding, much less even a
13 presumption that that is the case, and that is because a recall
14 is a different kind of regulatory action. It is not a finding
15 of misbranding, a violation of Federal law.

16 What this really comes down to is, what are the state
17 law requirements that Plaintiffs are trying to impose?

18 If you look at the consumer class action, it is rife
19 with allegations that amount to a head-on challenge to the
20 safety and efficacy of Zantac, Zantac as a molecule, the
21 Ranitidine molecule, as well as the Federally approved label
22 and formulation.

23 Plaintiffs acknowledge as much. What they do is they
24 fall back on a sliver of allegations that they say do lead --
25 do assert some kind of departure from Federal requirements.

1 They say that there might have been storage problems when
2 outside the storage limitations of the label, that perhaps
3 there was a manufacturing issue, perhaps there was a failure to
4 adhere to reporting requirements to FDA.

5 But those grabs at claims that are left are not
6 sufficient to state their claim, and that is something that I
7 think Plaintiffs in both the implied and the express preemption
8 realm obscure, which is the process that this Court should go
9 through is first strip away the vast majority of these
10 allegations that are preempted, and then the little slivers
11 that are left, then we will see if these amount to a claim that
12 can continue to state a cause of action.

13 Some of those little slivers might lead to a claim
14 that survives this preemption motion, but this Court should
15 narrow the theories of liability. I think that is one of the
16 key planks of Mr. Keller's presentation, is some kind of
17 assertion that what should happen at the end of the day is that
18 all of these preemptive theories should still survive so long
19 as some sliver of their claim could support a cause of action,
20 or any cause of action in these broad complaints.

21 That is not the way this should work, especially in an
22 MDL this size and scope. It is the normal course, but also the
23 appropriate course to strip away the preemptive theories of
24 allegation and to strip away the preemptive claims and then see
25 what is left.

1 And then, as your Honor knows, there is a third round
2 of Motions to Dismiss and we will see if any of these claims
3 end up surviving that third round when we have now narrowed the
4 field.

5 *THE COURT:* I just want to let you know you are at 13
6 minutes.

7 *MS. EISENSTEIN:* Ms. Horton covered, I believe, on the
8 design defect component the fact that the Plaintiffs have
9 really backed away from the design defect claim and have
10 resorted to redundant failure to warn claims. We have heard
11 nothing today that departs from that.

12 And just as in the express preemption realm, this
13 Court should strip away the preemptive theories in the implied
14 preemption context, strip away the design defect theories that
15 Plaintiffs have admitted multiple times even today that they
16 cannot proceed with because it is impossible for manufacturers
17 to modify the FDA approved design.

18 I will leave it at that, your Honor, and save a couple
19 of minutes for rebuttal.

20 *THE COURT:* Okay, thank you. We will have Mr. Keller
21 for the Plaintiffs for his 15 minutes.

22 *MR. KELLER:* Thank you, your Honor. Good afternoon,
23 Ashley Keller for the Plaintiffs.

24 I'll be talking about misbranding and some of the
25 points that were just raised. I will then turn to the

1 over-the-counter preemption argument under 379(r).

2 To begin, we have been sort of accused, I think, by my
3 friends on the other side of mischaracterizing the misbranding
4 statute. Your Honor, in my earlier remarks I quoted the
5 definition of misbranding directly from the Food, Drug and
6 Cosmetic Act and then I quoted the duties created by the
7 misbranding statute.

8 They, on the branded side, want to come up with this
9 alternative theory that they didn't ground in statutory text,
10 that they didn't ground in the Code of the Federal Register
11 that says as long as we complied with the FDA label back in
12 1983, and we affix that to the product, we cannot ipso facto as
13 a matter of law be accused of misbranding, and that is just
14 simply incorrect.

15 It appears nowhere in the text of the statute the
16 Supreme Court rejected that proposition in Footnote 4 in
17 Bartlett, which nobody has grappled with. I quoted the CFR
18 that says that that is not true. Even an FDA approved drug can
19 be misbranded if new and scientifically significant information
20 comes to light.

21 So, the brands are simply saying that because we
22 complied with the label you have to give us a get out of
23 liability free card, and that appears nowhere in the law.

24 I think it is also important to note, your Honor, that
25 the categories of Defendants don't seem to agree with each

1 other on what the misbranding statute is. I quoted the text,
2 they are making these other arguments and they are at cross
3 purposes with each other. For example, the generic
4 manufacturers incorporate by reference the brand briefing on
5 misbranding. This is in the generic reply at 10. But then
6 they contradict the brands.

7 The generic manufacturers say, this is in their reply
8 at 11, that misbranding claims can only apply to those that
9 bear no connection to the label. But the brands say just the
10 opposite at page 14 of their reply brief, and you just heard it
11 now. They say that by simply complying with the NDA and the
12 label that was affixed to the product by the FDA back in 1983,
13 we are automatically shielded from liability on misbranding.

14 So, neither of those propositions are consistent with
15 each other, neither of them are entirely correct. The Court
16 should just look to the statutory scheme to discover the
17 definition of misbranding. Congress put it in plain English.
18 Similarly, the duties associated with misbranding are stated in
19 plain English. There is no ambiguity surrounding that.

20 I have to clarify as well something that my friend
21 just said because I think she may have misheard me, and your
22 Honor can pull the transcript. I am not confident of that many
23 things, but I am a hundred percent positive on the following
24 point.

25 I never said, in response to your Honor's question,

1 that the FDA's requiring the Defendants through a voluntary
2 recall establishes misbranding as a matter of law. I said, no,
3 that by itself doesn't establish misbranding as a matter of
4 law, it is that coupled with the new scientific information
5 that we say in the well-pleaded complaints meets the definition
6 of misbranding.

7 Yes, a voluntary recall by itself is not proof of
8 misbranding, it is probative. The FDA didn't tell all of these
9 Defendants to pull Ranitidine from the shelves because it was
10 no big deal that NDMA was forming, but they didn't technically
11 go through the mandatory recall provision, and they didn't make
12 a misbranding finding, and we never stated anything to the
13 contrary.

14 There is a little bit of a technical point that is
15 going on here, your Honor, but technical points can still be
16 important so I want to respond to it. We say in our briefing,
17 and I am sure your Honor picked up on this, that Courts dismiss
18 claims, not theories. So, the Motion to Dismiss, if it is
19 going to be granted, has to be because we state no theory that
20 is possible to pursue consistent with Federal law.

21 My friend just said that my position previously was
22 that even though there are a bunch of theories that we now
23 recognize based on their arguments in their Motions to Dismiss
24 can't proceed under the supremacy clause, that we should just
25 ignore that and the theories should be allowed to move forward.

1 Absolutely not, that is not what I am saying. The theories
2 that are preempted cannot be pursued, but Courts don't dismiss
3 theories, they dismiss claims.

4 If there is a different theory that could support the
5 claim, even if it is narrower, that theory needs to be allowed
6 to proceed.

7 So, there is a little bit of us talking past each
8 other, but I think that that is an important point, that it
9 ties back in to all of the discussions we have been having
10 before about Bates and Mink and preemption only applying to the
11 extent of a difference between state and Federal law.

12 Our design defect claim can be stated with a theory
13 that the label was defective. Yes, that is a narrower theory
14 than saying the brands had to redesign the molecule, but it is
15 a viable theory under the law of New Hampshire, under the law
16 of basically every state. Bartlett embraced this. So, they
17 can't get dismissal of a design defect claim when there is an
18 available theory for us to pursue.

19 Let me turn to the over-the-counter provision, your
20 Honor, and there is, of course, an express preemption clause
21 here with a saving clause, and I will address them both
22 separately.

23 It is worth noting at the outset that the brand
24 manufacturers don't even move to dismiss our failure to warn
25 claim. So, at least for the purposes of a 12(b)(6) -- they

1 have, of course, reserved all of their rights for summary
2 judgment, but for purposes of a 12(b)(6), they acknowledge that
3 they could have changed the warnings and precautions section of
4 the label.

5 Maybe they also acknowledge that they could have
6 changed the expiration dates, but they certainly could have
7 changed the warnings and precautions section, because they know
8 that Wyeth versus Levine squarely holds that the CBE regulation
9 is available to them and they don't need the FDA's prior
10 permission or approval in order to make that sort of change.

11 How does that square with their argument on the
12 express preemption clause? Under the express preemption
13 clause, a state duty like failure to warn, to change the label
14 so that you add warnings and precautions about cancer is not
15 preempted to the extent that it is the same as Federal law, and
16 Federal law also requires them to have an accurate label.

17 When new and emerging science comes to light that
18 demonstrates that your label is inaccurate, it is not incumbent
19 on the FDA to tap you on the shoulder and say you need to make
20 this change. Wyeth versus Levine is crystal clear, the FDCA
21 places primary responsibility on the manufacturers to keep
22 abreast of this emerging science and new information.

23 So, they had a duty under state law and under Federal
24 law to change their labels. Those duties are completely
25 parallel with each other, and as a consequence, there can't be

1 preemption with respect to those claims.

2 Similarly with our misbranding theory, your Honor,
3 they had an obligation to stop selling a defectively designed
4 product. We have already marched through the statutory
5 definitions, and state law created the exact same duty as a
6 matter of design defect law. So, once again there is no
7 preemption on the terms of the express preemption clause
8 because state and Federal responsibilities are identical to
9 each other.

10 Let's turn to the saving clause, your Honor, because
11 even if you don't find that there are parallel claims, to the
12 extent that we are pursuing product liability law of any state,
13 that is expressly carved out of the express preemption clause.

14 The key point to note here, your Honor, is every
15 single case that the Defendants cite, Carter, Cantor, Mills,
16 and others, which they say we found a few cases, we didn't find
17 these cases, these are the brands' cases. They all look to the
18 law of the states to determine what a product liability claim
19 is, and that makes sense given the text of the saving clause.
20 It says the product liability law of any state.

21 The only response that they have to this, your Honor,
22 in their reply is to say, well, those cases that the Plaintiffs
23 found, even though the Defendants are the ones that cited them
24 and found them, those were a different context, those were
25 single cases. This is a big complex MDL sitting in diversity,

1 so it is more important here to have a Federal definition of a
2 product liability claim instead of relying on the uniform line
3 of authority that says you look to state law.

4 With all due respect, your honor, the definition of a
5 Federal statute doesn't turn on whether the case is complex or
6 not, or an individual case. Whether product liability law of
7 any state refers to state law or Federal law can't turn on the
8 complex manual for litigation in MDLs, which the brands also
9 cite. Every case that they cite points to state law, it is
10 uniform in that regard. And not all states have the same
11 definition of a product liability claim.

12 So, the only way that they can prevail under the
13 savings clause is to go state by state and point out the ones
14 that would define a product liability claim to defeat the
15 claims brought in the class complaints. They haven't met that
16 burden.

17 There are some states, we acknowledge, that would
18 define a product liability claim as one that would preclude
19 liability here, but the states are not uniform on this front,
20 and this is a theme that has recurred throughout these oral
21 arguments. Treating the states as the sovereign entities that
22 they are, with the nuances that they are allowed to have within
23 their own state system is the appropriate course of conduct.

24 It doesn't matter whether the MDL is complex, that is
25 the only approach that makes sense.

1 The final thing that I would like to conclude with,
2 your Honor, is that the challenge I set forth at the beginning
3 of these oral arguments has not been met. I asked any category
4 of Defendant to offer a single concrete example of parallel
5 claims where the state and Federal duties were the same, but it
6 was nonetheless impossible to comply with both. No one has met
7 this challenge, your Honor, because they cannot as a matter of
8 logic.

9 Instead, you have heard some citations, snippets of
10 cases that say just because you survive express preemption,
11 that doesn't mean that you survive implied preemption. We
12 heard about the Guarino case and others.

13 We agree that the Supreme Court has said in a case
14 called Guyer (phon) that just because you survive express
15 preemption, it doesn't mean you survive implied preemption.
16 How is that consistent with the challenge that I set forth
17 earlier? It is his consistent for two different reasons.

18 First, not every express preemption clause is as broad
19 as the one here under 379(r), or under the Medical Device Act.
20 Those are extremely broad express preemption clauses that
21 require identity between the state and Federal duties in order
22 for the state duties to survive preemption.

23 You could imagine narrower express preemption clauses
24 where there still might be some space for implied impossibility
25 preemption to exist, but not with these express preemption

1 clauses.

2 The other reason that Guyer is consistent with our
3 view, your Honor, is because implied impossibility is not the
4 only type of implied preemption. There is also objects and
5 purposes preemption or field preemption. Importantly, they
6 haven't briefed those branches of the preemption doctrine. If
7 they did, we would respond and they would lose, and I can
8 demonstrate why field and objects and purposes preemption have
9 no space here to preempt our claims, but that is beside the
10 point.

11 The Supreme Court was merely saying just because you
12 make it through express preemption, doesn't mean you don't have
13 to walk through the mine field of the other categories of
14 implied preemption. They were not talking specifically about
15 implied impossibility preemption, your Honor, and it is
16 impossible for there to be impossibility on the facts that we
17 allege here.

18 Thank you.

19 *THE COURT:* Thank you. Did the Defendants want to
20 come back on for any rebuttal?

21 *MS. EISENSTEIN:* Yes, your Honor. This is
22 Ms. Eisenstein.

23 Your Honor, let me start with Bartlett. Footnote 4
24 posed a hypothetical and left open the question of whether
25 misbranding could exist based on the lack of safety of a

1 product, but either before that time or since that time there
2 has been no case where that has occurred.

3 While misbranding -- compliance with the label is not
4 an antidote to misbranding if there was some other provision of
5 Federal law that was violated, there has to be a separate
6 provision of Federal law that is violated. Some Courts have
7 described misbranding as a derivative violation. It is
8 derivative of violations of other requirements of Federal law.
9 In and of itself it doesn't impose a free-standing criminal
10 violation for selling an unsafe product.

11 I want to point to something else that Mr. Keller just
12 said. He said that he recognized that this Court could dismiss
13 his claims to the extent they are preempted, and we agree.

14 I think the Mink case that Mr. Keller is very fond of
15 is illustrative because in Mink the Plaintiff wisely pled his
16 claim, state law claims, only to the extent they directly
17 paralleled the Federal claim. That was specified in the
18 decision, and that is in serious contrast to this wide-ranging
19 complaint that states allegation after allegation that directly
20 challenges the FDA approved label and design of Ranitidine.

21 So, what we ask is that those claims are dismissed to
22 the extent they are preempted.

23 And lastly, on product liability, the product
24 liability savings clause under 379(r), Mr. Keller says that we
25 need to go state by state.

1 Well, it is his burden, first of all, because it is a
2 savings clause. But even apart from that, even if we were to
3 look to state law, Plaintiffs have pointed to no state law that
4 imposes product liability, or characterizes product liability
5 as a refund claim. Refund claims are not product liability
6 claims. Product liability claims are claims that reach harms
7 that are derived from the use of the product, not a claim for
8 the refund itself.

9 In their briefing and here today they have pointed to
10 no case that puts refund claims in the category of product
11 liability under any state law.

12 I will conclude there and leave it to your Honor's
13 questions. Thank you.

14 *THE COURT:* Thank you. If we can have all counsel
15 come on. One last round of the same questions just so I am
16 crystal clear.

17 The Defendants' motion, preemption motion, stated that
18 it was a Rule 12 motion. Is it correct that the motion is a
19 12(b)(6) motion based on an affirmative defense?

20 *MS. EISENSTEIN:* Yes, your Honor.

21 *THE COURT:* Okay. Do you agree that impossibility
22 preemption means state law imposes a duty or obligation to do
23 something, but Federal law prevents you from doing it?

24 *MS. EISENSTEIN:* Yes.

25 *THE COURT:* For Plaintiffs, misbranding. The master

1 complaints do list several -- and we have talked about it at
2 length today, counsel have on both sides in their presentation.
3 The master complaints list several subsections of the Federal
4 statute defining misbranding. That is at 21 U.S.C Section 352,
5 which Mr. Keller cited into the record today. And that is also
6 at your master personal injury complaint, paragraph 419, and
7 the consolidated consumer class action complaint at 599, and
8 the consolidated third party payor class complaint at paragraph
9 185.

10 In pages 15 and 16 of your opposition where you
11 explain Zantac was misbranded, you cite only 21 U.S.C. Section
12 352(a)(1) and -- actually (a), I think it is (1) and (j).

13 Let me just look at your response. I want to make
14 sure I have -- no, it is 352(j), and then you have and Section
15 (a)(1).

16 So that the Court is clear, are subsections (a)(1) and
17 (j) of Section 352 the only subsections that you maintain are
18 at issue? And if not, could you specifically identify the
19 other subsections that you maintain apply in this case?

20 *MR. KELLER:* Ashley Keller for the Plaintiffs, your
21 Honor. For purposes of the definition of misbranding that we
22 offered, I believe these are the only sections that we were
23 referring to.

24 *THE COURT:* Are any other subsections at issue in the
25 misbranding statute?

1 MR. KELLER: Ashley Keller again for the Plaintiffs,
2 your Honor. For purposes of the definition or just at large
3 for the other --

4 THE COURT: Including the other propositions. It was
5 unclear from your briefing, matching it up with your
6 allegations in your complaint, so I just want to make sure I
7 understand.

8 MR. KELLER: Understood, your Honor. The next page,
9 so Section 331, is also definitely at issue. That is what
10 announces the duties associated with the misbranding
11 definition. That is a crucially important provision of the
12 statute that we also think is relevant.

13 For purposes of rebutting some of the points that you
14 have heard and that we didn't see until the reply briefs came
15 in, there may be other sections relevant like the good faith
16 carve out which is, I believe, contained in Section 333, and
17 the criminal penalties contained in Section 333(a)(1).

18 But for purposes of our main argument, it is 352 and
19 331.

20 THE COURT: Do you know of any states that recognize
21 causes of action sounding in "misbranding" that you maintain
22 are parallel to the Federal misbranding statutes?

23 MR. KELLER: Ashley Keller again, your Honor. Yes,
24 the duties created by state law I think almost uniformly would
25 apply, but the title of the cause of action is not misbranding,

1 it is design defects. That is why in my opening remarks I
2 reminded the Court of the teaching of *Bates*, which is that
3 state law doesn't have to use the same phraseology as Federal
4 law. They don't have to title their cause of action
5 misbranding. As the Court said in *Bates*, it would be unusual
6 and surprising for the states to do that. That is not how they
7 announce their common law. It is just that the duties have to
8 match.

9 No. To answer your question with a yes or no, no, I
10 am not aware of states that call the cause of action
11 misbranding, but the duties created by the state causes of
12 action parallel the misbranding duties.

13 *THE COURT:* And those causes of action would include
14 design defect causes of action, and what other types causes of
15 action?

16 How would one survey all state laws to ascertain a
17 duty that one can glean from a state statute among many state
18 statutes that, based on the argument you were making earlier,
19 that even if there are many duties, and some of those duties
20 are in conflict, as long as there is one duty that may be
21 parallel to a Federal duty such that it is not impossible to
22 fulfill or to meet that duty? What does that look like?

23 *MR. KELLER:* A good question, your Honor. I am happy
24 to narrow it for the Court so that it's an easier inquiry.

25 We will rest it on design defect for purposes of the

1 duty to not sell a defectively designed product in this regard.
2 The Supreme Court accepted that in Bartlett under New Hampshire
3 law, as we noted. But this would be true of common law design
4 defect throughout the 50 states. There would be an obligation
5 to stop selling a defectively designed product. So, if you
6 focus on design defect, I think that will get you there.

7 The consequences of recognizing the stop selling duty,
8 to the extent the facts establish misbranding, could have
9 impacts on other claims, but because Bartlett has already
10 accepted the formulation under design defect law, I think it is
11 easiest to focus on that for purposes of this analysis.

12 *THE COURT:* Have the Plaintiffs undertaken that
13 analysis of all design defect laws in all states to ascertain
14 which claims may survive an impossibility preemption?

15 *MR. KELLER:* Ashley Keller for the Plaintiffs. We
16 haven't conducted a 50 state survey of design defect causes of
17 action. We know that we have binding Supreme Court precedent
18 on one state, the state of New Hampshire, but I surmise that
19 the law is going to be the same everywhere having looked at
20 enough different states on design defect and the duties
21 associated with it.

22 For purposes of a master personal injury complaint, I
23 think it is sufficient if even a single state lets this theory
24 go forward and, obviously, once we are not dealing with
25 cross-cutting issues anymore, but we're focused on specific

1 Plaintiffs at the bellwether phase or some subsequent round of
2 motion practice, it may be more appropriate to zero in once a
3 choice of law analysis has been done on particular state law.

4 *MS. EISENSTEIN:* May I respond to that, your Honor?

5 *THE COURT:* You may.

6 *MS. EISENSTEIN:* Your Honor, I just feel I need to
7 respond to what Mr. Keller said about Bartlett. Bartlett did
8 not accept that misbranding is an exception to implied
9 preemption. In fact, it said exactly the opposite. It
10 directly rejected the idea that stop selling is an exception to
11 implied preemption when a manufacturer cannot comply with
12 Federal law. It says so explicitly. It says --

13 *THE COURT:* Wait. When you put your head down it made
14 it difficult for us to hear.

15 *MS. EISENSTEIN:* I'm sorry. So, Bartlett rejected
16 exactly the point that Mr. Keller is suggesting, that somehow
17 there is an exception to implied preemption where a
18 manufacturer can otherwise -- it is impossible for the
19 manufacturer to comply with both the state law and the Federal
20 duty that stop selling is the result.

21 In fact, it said that explicitly. It says preemption
22 law does not presume that an actor seeking to satisfy both his
23 Federal and state obligations that it is not required to stop
24 acting in an attempt to avoid liability.

25 What Mr. Keller said is wrong both as a matter of

1 Footnote 4, which related to a hypothetical and was not
2 something that the Supreme Court decided, but it also is wrong
3 with respect to the conclusion for implied preemption. If it
4 is the case that as designed and labeled under Federal law,
5 that states would have deemed it a design defect, the result is
6 not stop selling. The result is that state law theory of
7 design defect is preempted.

8 MR. KELLER: Your Honor, can I briefly respond to
9 that?

10 THE COURT: You may.

11 MR. KELLER: Ashley Keller for the Plaintiffs. I
12 think once again my friend and I are talking past each other.
13 When I quoted Footnote 4 in Bartlett what I was rejecting was
14 the brands' argument that just because they have the FDA
15 approved label on their product that shields them from
16 misbranding.

17 Footnote 4 says the opposite. "The misbranding
18 statute requires a manufacturer to pull even an FDA approved
19 drug from the market when it is dangerous to health, even if
20 used in the dosage or manner or with the frequency or duration
21 prescribed, recommended, or suggested in the labeling thereof."

22 I never said that Bartlett embraced our theory. I was
23 candid with the Court in my opening, I'll be candid with the
24 Court again, Bartlett left the question open. We are not
25 saying that Bartlett squarely embraced the theory that we are

1 pursuing. It left it open.

2 And the cases that have addressed this situation since
3 have also left the question open. The Sixth Circuit case that
4 you heard about in Darvocet, it didn't reject the misbranding
5 theory, it said we don't need to decide it because the Supreme
6 Court left the question open in a narrow set of circumstances.
7 It is not opening the barn doors for any type of misbranding
8 theory to proceed. There has to be new and scientifically
9 significant information that the FDA never previously
10 considered.

11 That is our case, not the Darvocet case. That is our
12 case, not Bartlett. I have never over stated Bartlett to this
13 Court. I agree that the question is an open one and your Honor
14 is free to answer it.

15 *MS. EISENSTEIN:* Your Honor, I just wish that Mr.
16 Keller would read the entirety of Footnote 4 instead of
17 exerting the key portion where the Supreme Court says we do not
18 reach. So I think that is very telling that he read the
19 portion that goes to (inaudible).

20 *THE COURT:* Wait, wait, Ms. Eisenstein. Why don't you
21 start over. Maybe you are too close to the microphone.

22 *MS. EISENSTEIN:* Your Honor, thank you very much.
23 This is Ms. Eisenstein.

24 What I was hoping was that Mr. Keller would read the
25 entirety of Footnote 4, instead of only the portion where he

1 talks about the requirement. What he misses, we do not reach
2 the issue that was raised as a hypothetical by the Government.
3 He doesn't hit at all the actual holding of Bartlett which said
4 that stop selling is not an antidote to implied preemption.

5 He makes this logical leap based on this concept of --
6 hypothetical concept of misbranding that Bartlett did not
7 recognize, and then tries to import something that directly
8 contravenes the actual holding of the Supreme Court's case.

9 *THE COURT:* Be assured, both sides, that I have
10 Bartlett, I have Footnote 4 in front of me, and I appreciate
11 the positions articulated and I think we can move on from that
12 particular question.

13 Question for Plaintiffs. Mr. Keller, the Defendants
14 contend that your claims for economic loss, refunds in other
15 words, for over-the-counter Zantac are preempted pursuant to
16 21 U.S.C. Section 379r. Pursuant to that statute, consumers
17 may not bring claims for economic harm under state laws that
18 are different than, in addition to, or otherwise not identical
19 to Federal requirements under the FDCA.

20 You contend, that is the Plaintiffs, Plaintiffs'
21 claims are not preempted because Section 379r(e) contains a
22 preemption carve out, which you have referenced today, and the
23 statute doesn't apply to state product liability law, and that
24 some states permit economic damages under product liability
25 law.

1 You and I got into this a little bit already, so it
2 might be a bit repetitive. This is discussed on page 30 of
3 your response where you say that "several" states permit
4 economic loss for a product liability claim. This is a little
5 bit different question.

6 Do you concede that if a specific state does not
7 permit a recovery for a specific type of injury, economic loss
8 here, a refund that is for a purchase price, under a product
9 liability claim that your claim for the same would be
10 preempted?

11 *MR. KELLER:* Ashley Keller for the Plaintiffs, your
12 Honor. I would concede that we would fall outside of the
13 saving clause. I don't think I would technically call that
14 preemption, I would say the state doesn't recognize the claim,
15 but we would lose either way. It would be a 12(b)(6)
16 dismissal.

17 The only caveat, though, is before you get to the
18 savings clause, you first have to see that there are
19 nonparallel claims. So, to the extent that we can allege a
20 breach of identical duties, and they have to be identical,
21 that is what it means for the claims to be parallel, we don't
22 even need to get to the savings clause and have a fight over
23 the definition of products liability law.

24 And with respect to the brands, there are some
25 parallel claims, as we note in the brief. Once again

1 misbranding, I won't go back to Footnote 4, taking your Honor's
2 admonition that you have it in front of you. And with respect
3 to the brands in particular, there are claims with respect to
4 the labeling, and they don't move the dismiss our failure to
5 warn claims label. So, they recognize that they could have
6 complied with state duties in that regard.

7 If our claims hinge on those theories, on those
8 duties, we don't get to the savings clause, but yes, if we are
9 in the territory of the savings clause, and a particular state
10 says, no, we don't recognize your right to seek money damages,
11 that doesn't fall within our definition, for example,
12 California of a products liability claim. I wouldn't call it
13 preemption, but we would lose.

14 *MS. EISENSTEIN:* May I respond, your Honor, to the
15 last point about the warning?

16 *THE COURT:* Yes.

17 *MS. EISENSTEIN:* Mr. Keller said this a couple of
18 times, that we somehow conceded that claims based on warnings
19 express preemption because we didn't move to dismiss as a
20 matter of implied preemption. We didn't move to dismiss
21 (inaudible).

22 I want to note, first of all, that we do not make that
23 concession that we (inaudible) claims that challenge the label
24 of Zantac or Ranitidine were expressly preempted. Court after
25 Court has held that.

1 I don't think Mr. Keller is really suggesting that it
2 is something other than that, but I also want to make clear
3 that we are not conceding that there is a (inaudible) failure
4 to warn claim.

5 *THE COURT:* Wait, wait, wait.

6 *MS. EISENSTEIN:* Is that better?

7 *THE COURT:* I think it is. For purposes of the
8 transcript, I was able to hear you, but I am not recording in
9 the same difficult manner that Ms. Stipes is. If you could
10 pick up with, I want to make clear, so if you want to state
11 your argument again so we make sure we get it on the record.

12 *MS. EISENSTEIN:* Sure. I apologize for the sound. I
13 hope it is better now.

14 I wanted to be clear, in response to Mr. Keller's
15 argument, that by not raising an implied preemption failure to
16 warn claim that we are in no way conceding that issue, but we
17 certainly are not conceding that as a matter of express
18 preemption that challenges to the FDA approved label are not
19 expressly preempted. They are expressly preempted.

20 Every Court to have addressed the question of whether
21 a direct challenge to the FDA approved label has found that
22 that falls squarely within the express preemption provision.

23 There is good reason for that. There is a window here
24 between what is possible to do as a matter of label changes and
25 what constitutes an additional, or different, or nonidentical

1 requirement, and it is clear that imposing a label that is
2 something other than what the FDA approved is a different,
3 additional, or nonidentical requirement that falls within the
4 express preemption provision.

5 *MR. KELLER:* Your Honor, may I touch on that point?

6 *THE COURT:* Yes.

7 *MR. KELLER:* Thank you, your Honor. I think my friend
8 keeps putting words into my mouth and saying that I was not
9 trying to suggest that there could be parallel claims. Yes, I
10 absolutely am trying to suggest that.

11 The FDA's position is that when a brand manufacturer
12 has the ability to make a labeling change because new
13 information has come to light requiring the manufacturer to
14 change the warnings and precautions section under state law, it
15 is also required by Federal law. It is a floor and a ceiling
16 according to the FDA.

17 So, it is not just implied impossibility preemption
18 that would not apply, it would also be express preemption that
19 would not apply if the FDA is correct on this score. Brand
20 manufacturers have to change their labels on the basis of new
21 information, it is not an option.

22 So, that is the difference between implied versus
23 express preemption here where they are both requirements, as
24 opposed to the Federal law saying you can if you want and state
25 law saying you have to. That would be a situation where there

1 wouldn't be implied preemption, but there would be express
2 preemption.

3 Here there is a requirement for both, so we think the
4 labeling argument applies to the express preemption clause. My
5 friend can disagree with that, but that is actually what I was
6 implying.

7 *MS. EISENSTEIN:* May I disagree, your Honor?

8 *THE COURT:* Let me go back. I want to ask Mr. Keller
9 a question that was a followup from the previous question
10 regarding the injury and if a state did not permit a recovery
11 for a specific type of injury, economic loss.

12 So, if the Court permitted Plaintiffs to replead,
13 should there be a scenario where there would be some
14 repleading, and provided you specified which states permit
15 recovery for an injury in the form of a purchase price, a
16 refund under a product liability theory, do you know
17 approximately how many states would be pled?

18 *MR. KELLER:* Ashley Keller for the Plaintiffs, your
19 Honor. I don't. I came armed with one example of a state
20 where we think we could survive, Arkansas. I don't have a
21 50-state survey yet, but because I have at least one, I think
22 that we would get through and at least some Plaintiffs would be
23 able to rely on that state's law, assuming you agreed with us,
24 and the uniform line of authority that you should be looking to
25 state law, not Federal law.

1 I have one illustration and, of course, we would
2 search all of the other 49 states and the two territories and
3 give the Court our best guess based on defining what the state
4 law says and making Erie predictions and things of that nature.

5 *THE COURT:* For Defendants, you contend that instead
6 of looking to state law to determine which states allow for
7 recovery of the purchase price under a product liability
8 theory, that the Court should look to Federal common law.

9 Do you have any citation to a case where a Court
10 relied upon Federal common law to interpret or apply Section
11 379(r)?

12 *MS. EISENSTEIN:* Not to 379(r) specifically, your
13 Honor, and the cases -- the very few cases that have addressed
14 this, which are cases that we cited in our own brief, cases
15 like Cantor and Mills -- I am sorry, Carter and Mills, the
16 Courts have looked to the state law, we acknowledge that, but
17 in other contexts -- in those particular cases it was really
18 one state law at issue, it wasn't a multi-state MDL, and it
19 really didn't make a difference ultimately to the outcome in
20 the case.

21 Here we still don't think it actually makes a
22 difference to the outcome of the case because we have
23 undertaken the exercise of looking at the state laws, and the
24 vast majority of states don't define product liability at all.
25 So, it would be very odd for Congress to have defined the

1 savings clause where most states don't have a definition of
2 product liability per se.

3 You could look to the law of torts or the type of
4 torts that generally are considered product liability, and
5 there we have looked at the law of all of the states and we
6 found none that characterize this kind of refund claim as
7 something that could fairly be characterized as a product
8 liability claim. We have put in that work and we don't see it.

9 I would also note that the economic loss doctrine,
10 which I think was referred to about purely economic harms that
11 flow from the use of the product might be recoverable, is a
12 different issue. So, there is the refund of the price itself,
13 and then there are some states that recognize that economic
14 harms that flow down, purely economic harms, a minority of
15 states, that flow down from the use of the product standing
16 alone can still constitute a claim.

17 That is not even at issue here, it is this first
18 refund claim piece, that there is simply no state that
19 recognizes such a claim as anything remotely defined as a
20 product liability action.

21 *THE COURT:* Okay, all right. That concludes the
22 questioning for that motion, so, thank you both.

23 And that does conclude our day as all motions have now
24 been heard that the Court had set to be presented over these
25 past two days.

1 So, with that, I want to thank everyone. I know they
2 have been two long days and we have had many people either
3 presenting and/or participating by listening and watching, and
4 I want to thank you for your patience over the two days. I
5 want to thank all of the attorneys for careful preparation both
6 in your briefing and in your oral presentation to the Court.
7 It has been most helpful.

8 At this point, the Court will endeavor to prepare the
9 orders that address the motions in a timely and expeditious
10 manner so as to be able to keep the case moving along in a
11 manner that is consistent with the deadlines that have been set
12 forth in the case management schedule. That is the Court's
13 task.

14 I will look forward to seeing some, if not many or all
15 of you, later in the week when the Court has set a status
16 conference on Friday where we will take up other matters, but
17 for purposes of our oral arguments on the first round Motions
18 to Dismiss this does conclude our proceeding.

19 Thank you very much. Everyone be well, have a nice
20 rest of the day and evening.

21 *(Thereupon, the hearing was concluded.)*

22 * * *

1 I certify that the foregoing is a correct transcript
2 from the record of proceedings in the above matter.

3
4 Date: December 21, 2020

5 /s/ Pauline A. Stipes, Official Federal Reporter

6 Signature of Court Reporter
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Pauline A. Stipes, Official Federal Reporter

<p>MR. AGNESHWAR: [4] 4/16 5/12 6/4 6/16</p> <p>MR. BARNES: [7] 7/12 7/21 7/24 8/3 8/13 8/15 15/24</p> <p>MR. GILBERT: [1] 4/6</p> <p>MR. GUGERTY: [5] 20/20 53/25 54/3 54/6 54/9</p> <p>MR. KAPLAN: [11] 66/15 66/18 67/1 67/21 67/23 79/1 106/8 106/21 114/21 115/23 124/10</p> <p>MR. KELLER: [54] 23/6 23/10 38/11 38/17 39/7 39/13 39/17 40/8 40/21 41/15 44/14 46/13 47/9 47/25 48/13 50/18 55/15 55/17 58/21 60/16 61/4 61/16 62/22 65/6 73/23 91/7 107/9 107/18 108/10 108/12 110/4 111/8 112/14 113/12 115/1 115/11 118/18 121/2 121/4 122/19 124/1 134/21 146/19 146/25 147/7 147/22 148/22 149/14 151/7 151/10 154/10 157/4 157/6 158/17</p> <p>MR. YOO: [12] 37/17 37/20 38/2 38/7 39/4 42/13 42/15 48/20 48/22 52/25 57/8 57/10</p> <p>MS. EISENSTEIN: [18] 125/5 125/16 129/2 134/6 143/20 145/19 145/23 150/3 150/5 150/14 152/14 152/21 155/13 155/16 156/5 156/11 158/6 159/11</p> <p>MS. HORTON: [2] 125/20 125/24</p> <p>MS. JOHNSTON: [9] 80/21 81/22 82/6 106/6 106/17 106/20 120/7 120/10 124/15</p> <p>MS. KAPKE: [2] 87/5 101/2</p> <p>THE COURT: [110] 2/18 4/8 4/17 6/1 6/12 6/17 7/20 7/22 7/25 8/11 8/14 15/20 20/18 23/2 23/8 37/7 37/19 37/21 38/4 38/10 38/14 38/21 39/6 39/9 39/14 40/2 40/18 41/6 42/14 44/13 45/25 47/2 47/22 48/10 48/19 48/21 50/12 51/17 54/2 54/4 54/8 55/14 55/16 57/9 58/7 59/25 61/1 61/9 62/9 64/9 66/3 66/16 66/23 67/12 67/22 73/20 78/24 79/23 80/12 81/12 82/1 91/3 100/24 105/19 106/10 106/19 106/25 107/13 108/5 108/11 109/8 110/7 112/3 113/3 114/23 115/7 115/22 118/11 120/9 121/3 122/4 123/21 124/4 124/17 125/14 125/19 125/22 134/4 134/19 143/18 145/13 145/20 145/24 146/23 147/3 147/19 148/12 149/11 150/4 150/12 151/9 152/19 153/8 155/15 156/4 156/6 157/5 158/7 159/4 160/20</p>	<p>/</p> <p>/s [1] 162/5</p> <p>1</p> <p>10 [1] 136/5 1001 [1] 2/2 10019 [1] 1/17 10402988 [1] 104/14 11 [8] 2/5 81/15 81/18 81/19 85/2 118/10 119/16 136/8 1159 [1] 22/23 12 [25] 7/3 21/22 36/15 37/16 37/17 37/18 45/18 57/8 62/19 66/12 80/15 93/12 102/12 106/4 106/5 118/21 119/21 124/7 124/9 124/23 138/25 139/2 145/18 145/19 154/15</p> <p>120 [1] 116/16 125 [1] 10/15 1292 [1] 50/11 12:02 [1] 80/2 13 [3] 85/11 91/4 134/5 14 [1] 136/10 15 [13] 1/5 12/20 49/11 62/13 64/12 66/24 67/10 74/1 80/18 81/18 125/15 134/21 146/10</p> <p>150 [1] 1/12 1580 [2] 80/3 124/22 1582 [2] 7/2 66/5 1583 [7] 66/10 66/23 80/5 105/21 105/23 106/3 124/19 1584 [9] 67/16 80/3 80/4 80/5 80/14 105/21 105/23 106/3 124/20</p> <p>16 [1] 146/10 1791.1 [1] 65/4 18 [3] 7/15 8/4 125/1 185 [1] 146/9 19 [2] 7/15 49/20 19103 [1] 2/10 1983 [7] 23/20 24/13 24/25 28/22 30/7 135/12 136/12</p> <p>1996 [1] 109/21 1:15 [3] 80/1 80/2 80/11</p> <p>2</p> <p>20 [3] 7/7 20/19 81/19 20 and [1] 49/10 20-md-02924-ROSENBERG [1] 1/3 20-minute [1] 23/5 20004 [1] 2/2 2001 [1] 52/16 2004 [1] 38/23 2011 [1] 52/8 2013 [1] 24/19 2013, no [1] 99/12 2017 [4] 14/16 48/15 52/18 104/14 202-624-2500 [1] 2/3 2020 [2] 1/5 162/4 2029 [1] 1/23 21 [19] 15/2 20/11 28/7 28/12 29/3 35/10 35/23 43/22 51/19 60/5 74/20 75/14 76/20</p>	<p>99/11 110/17 110/25 146/4 146/11 162/4 21 U.S.C [1] 153/16 211.166 [1] 35/17 212-836-8011 [1] 1/18 21202 [1] 2/14 213-896-2400 [1] 1/21 215-656-3307 [1] 2/11 23 [3] 7/6 8/1 91/5 2311 [5] 21/13 21/19 62/14 64/12 73/13 24 [2] 51/20 60/6 2400 [1] 1/21 25 [1] 10/18 250 [1] 1/17 2500 [1] 2/3 26 [2] 20/19 110/18 269 [1] 103/25 269416 [1] 103/25 27 [1] 110/18 2924 [1] 3/4</p> <p>3</p> <p>30 [2] 49/11 154/2 300 [1] 1/23 302 [1] 45/5 310-284-3798 [1] 1/24 312-741-5222 [1] 1/14 314.170 [1] 29/3 314.70 [3] 20/12 36/2 43/22 314.71 [1] 35/23 314.94 [1] 35/11 314.97 [1] 35/20 317-509-9545 [1] 2/6 32 [2] 46/4 62/11 320 [1] 127/3 33 [2] 62/12 62/18 3307 [1] 2/11 331 [6] 28/12 74/20 75/3 75/14 147/9 147/19 333 [6] 75/14 75/15 75/16 75/21 147/16 147/17 333's [1] 101/12 334 [1] 76/21 337 [1] 49/2 34 [1] 64/15 341 [1] 52/16 342 [1] 22/7 35 [1] 4/23 352 [8] 28/7 28/9 130/12 146/4 146/12 146/14 146/17 147/18 360 [2] 15/3 83/21 360eee [1] 110/17 360eee-4 [4] 99/12 111/1 111/14 123/2 373 [1] 45/5 379 [9] 31/6 69/9 127/9 127/21 135/1 142/19 144/24 159/11 159/12 3798 [1] 1/24 379r [2] 153/16 153/21 385 [1] 45/5</p> <p>4</p> <p>40 [2] 23/20 29/7 400 [1] 1/20 4000 [1] 2/14</p>
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4	402 [1] 109/21 404 [1] 109/21 407 [8] 77/11 114/9 114/25 115/3 115/9 116/5 116/12 119/3 408 [2] 120/15 120/21 409 [1] 115/2 410-783-4000 [1] 2/14 416 [1] 103/17 419 [1] 146/6 423 [1] 45/5 425 [1] 22/6 4270 [1] 1/13 453 [1] 27/2 454 [1] 26/16 457 [1] 115/3 46204 [1] 2/6 47 [1] 22/23 481 [2] 45/5 71/13 486 [1] 45/5 49 [2] 128/14 159/2 495 [1] 27/16 496 [1] 46/6	8011 [1] 1/18 874 [1] 52/17 889 [1] 88/6 8th [1] 1/20	according [10] 4/23 11/19 19/11 19/20 42/23 99/1 102/22 118/5 120/16 157/16 accuracy [2] 9/21 40/17 accurate [9] 34/25 40/10 40/14 41/2 41/4 44/18 64/5 65/15 139/16 accuse [1] 26/17 accused [2] 135/2 135/13 accused of [1] 135/13 accuses [1] 29/10 achieves [1] 23/23 acknowledge [7] 59/11 117/17 132/23 139/2 139/5 141/17 159/16 acquainted [1] 9/15 across [1] 16/12 act [56] 10/11 20/24 21/10 21/10 21/20 30/19 30/24 31/4 31/24 43/4 62/11 62/13 62/14 64/13 64/16 64/21 67/6 69/9 69/14 69/17 69/20 69/22 70/3 71/24 72/3 72/17 76/12 81/3 87/3 87/8 87/10 87/14 87/24 88/4 88/8 90/9 90/15 90/15 90/24 98/16 101/18 102/14 102/25 103/21 105/5 110/10 110/13 110/23 122/6 122/9 122/24 123/3 123/15 127/7 135/6 142/19 Act and [1] 90/15 act's [1] 88/10 acted [1] 5/7 acting [2] 108/1 150/24 action [59] 9/7 11/8 12/8 12/21 14/11 17/19 18/4 19/21 26/18 27/4 34/9 53/12 55/3 57/15 58/13 58/14 58/16 59/1 59/2 59/6 59/13 59/16 59/19 59/23 69/2 71/19 76/3 76/9 85/2 95/7 95/12 106/25 107/8 107/13 108/16 109/15 118/24 128/13 129/14 130/3 130/19 131/22 132/1 132/14 132/18 133/12 133/19 133/20 146/7 147/21 147/25 148/4 148/10 148/12 148/13 148/14 148/15 149/17 160/20 actionable [1] 122/4 actions [3] 19/6 50/18 54/16 actor [1] 150/22 actual [3] 57/11 153/3 153/8 actually [19] 12/25 13/5 14/9 31/5 37/8 64/5 67/2 91/19 109/18 116/10 116/22 117/1 120/13 120/14 123/17 124/22 146/12 158/5 159/21 add [5] 59/10 118/11 120/12 129/23 139/14 add warnings [1] 139/14 added [2] 10/9 42/9 adding [1] 11/2 addition [6] 15/4 31/7 90/11 90/17 127/11 153/18 additional [7] 10/9 27/11 27/12 48/6 110/24 156/25 157/3 address [18] 3/9 4/8 23/1	
5	50 [8] 47/5 47/9 47/15 95/18 98/7 112/17 149/4 149/16 50 degrees [2] 112/7 112/9 50-degree [1] 112/19 50-state [1] 158/21 5000 [1] 2/10 51 [1] 47/17 52 [1] 72/25 5222 [1] 1/14 531 U.S. 341 [1] 52/16 536 [1] 46/6 55 [2] 112/18 114/5 55 degrees [2] 112/11 114/5 552 of [1] 45/5 55th [1] 1/17 564 [2] 14/12 52/7 570 [1] 71/12 599 [1] 146/7	9 90 [1] 83/10 90067 [1] 1/24 90071 [1] 1/20 939 [1] 109/20 9545 [1] 2/6	A a finding [1] 132/14 a retailer [1] 108/9 a safer [1] 52/10 a saving [1] 138/21 a suspect [1] 89/4 abandoned [1] 85/4 ability [5] 70/13 70/16 84/16 94/4 157/12 able [6] 4/2 4/2 4/12 156/8 158/23 161/10 ably [1] 101/7 about [67] 3/15 5/15 5/15 5/17 7/15 8/4 8/9 16/24 19/10 20/19 24/10 24/19 25/9 25/12 26/20 26/21 27/10 30/25 32/25 35/15 43/7 49/18 52/11 53/5 55/3 55/8 56/25 61/8 66/17 73/16 74/4 74/9 76/5 80/1 91/4 91/20 91/25 92/17 92/17 97/13 98/9 100/20 103/13 110/17 114/10 114/23 115/3 122/7 122/24 123/1 123/2 123/9 123/9 123/10 126/2 129/11 134/24 138/10 139/14 142/12 143/14 146/1 150/7 152/4 153/1 155/15 160/10 above [3] 108/1 112/9 162/2 abreast [3] 32/16 34/3 139/22 absolute [21] 71/5 71/10 71/17 71/19 75/6 95/1 95/10 95/12 95/14 97/3 98/3 102/4 102/8 102/13 102/13 107/7 107/12 109/10 109/14 111/17 112/2 absolutely [5] 6/17 86/16 109/12 138/1 157/10 absolve [4] 48/3 53/14 53/18 121/16 absolved [2] 36/24 42/2 absurd [1] 99/1 accept [14] 13/23 14/3 17/19 18/13 34/17 89/8 102/12 110/14 110/16 110/20 111/3 111/6 111/10 150/8 accepted [5] 13/17 27/23 114/12 149/2 149/10 accepting [4] 86/4 88/24 89/18 89/24 accepts [1] 124/12 access [6] 50/23 51/8 51/15 77/17 115/16 123/14 accommodation [1] 4/5 accordance [2] 79/15 113/7	
6	60 [2] 95/18 98/7 604 [2] 34/11 52/7 60606 [1] 1/13 619 [3] 34/11 52/7 52/12 620 [1] 14/12 621 [1] 14/12 624 [1] 52/7 669 [1] 88/5 675 [1] 88/5 696 [1] 103/17	8 80 [4] 47/5 47/16 112/11 114/5		
7	70 [2] 95/18 98/7 70 degrees [1] 47/9 717 [1] 52/17 75 degrees [1] 47/7 772.467.2337 [1] 2/18			

<p>A</p> <p>address... [15] 29/8 67/8 71/16 74/6 79/4 80/5 87/3 91/2 98/14 101/4 103/10 103/14 127/2 138/21 161/9</p> <p>addressed [6] 10/8 18/19 72/1 152/2 156/20 159/13</p> <p>addresses [2] 65/9 113/15</p> <p>addressing [2] 4/21 82/14</p> <p>adequacy [1] 9/21</p> <p>adhere [5] 46/25 48/24 98/1 98/12 133/4</p> <p>adhered [1] 46/19</p> <p>Administration [1] 14/6</p> <p>admit [1] 97/20</p> <p>admitted [1] 134/15</p> <p>admitting [2] 80/10 86/6</p> <p>admonition [1] 155/2</p> <p>adopt [1] 17/16</p> <p>adopted [1] 17/15</p> <p>adulteration [2] 29/4 79/17</p> <p>advance [2] 64/19 94/19</p> <p>advanced [1] 86/13</p> <p>affect [1] 20/10</p> <p>affected [1] 44/4</p> <p>affects [1] 43/24</p> <p>affiliates [1] 6/3</p> <p>affirmations [2] 65/3 73/5</p> <p>affirmative [8] 37/17 94/9 94/20 106/6 114/2 121/21 121/22 145/19</p> <p>affirmed [1] 10/19</p> <p>affix [2] 28/20 135/12</p> <p>affixed [1] 136/12</p> <p>afield [1] 14/20</p> <p>after [12] 3/20 28/23 35/7 61/14 67/15 80/3 103/20 105/23 119/24 131/2 144/19 155/24</p> <p>afternoon [7] 80/22 82/7 91/8 125/6 125/21 125/23 134/22</p> <p>again [64] 13/10 17/13 19/5 19/22 23/12 27/2 27/19 32/2 32/13 32/19 34/7 34/20 36/20 37/10 37/22 38/15 38/17 40/1 40/3 41/7 45/8 46/24 48/2 48/11 51/7 51/15 56/5 59/1 62/8 62/24 65/8 68/11 71/25 74/11 74/20 75/3 76/3 77/16 78/2 82/7 90/8 95/24 98/16 99/23 100/20 107/19 108/17 108/19 109/15 110/6 111/21 114/1 114/15 115/13 116/6 121/6 121/20 140/6 147/1 147/23 151/12 151/24 154/25 156/11</p> <p>against [43] 10/16 12/18 17/20 18/5 22/10 22/18 68/17 68/23 68/24 69/5 69/7 69/10 70/10 70/22 71/22 72/6 73/9 76/23 83/17 85/2 85/15 85/19 86/5 86/7 86/12 87/16 89/10 92/23 92/25 93/1 93/8 94/6 95/7 95/19 100/6 104/10 107/8 109/23 112/22 117/8 123/24 124/6 126/13</p>	<p>agencies [2] 32/8 33/9</p> <p>agency [7] 24/19 25/1 32/8 32/16 34/3 39/23 56/3</p> <p>AGNESHWAR [4] 1/16 4/11 4/16 5/14</p> <p>ago [9] 10/13 10/14 23/20 24/18 25/22 29/7 30/15 98/8 107/6</p> <p>agree [36] 25/1 30/7 30/23 33/12 37/24 38/5 38/12 38/19 42/4 46/14 46/24 65/12 79/18 91/12 91/17 94/12 94/23 97/19 98/16 98/18 106/15 106/21 106/23 109/4 109/24 112/12 119/16 120/3 120/5 124/17 129/18 135/25 142/13 144/13 145/21 152/13</p> <p>agree it [1] 33/12</p> <p>agreed [3] 6/20 104/24 158/23</p> <p>agreeing [1] 6/22</p> <p>agreement [1] 39/2</p> <p>agrees [2] 64/2 118/9</p> <p>ahead [1] 66/18</p> <p>aid [2] 3/16 3/22</p> <p>air [2] 77/25 86/21</p> <p>akin [1] 109/16</p> <p>albeit [1] 5/6</p> <p>alerting [1] 96/18</p> <p>aligned [1] 24/22</p> <p>all [112] 3/5 3/24 6/11 6/13 8/12 8/15 10/12 11/9 11/13 12/8 12/20 13/5 13/8 15/19 16/4 17/23 19/5 20/21 21/2 23/16 23/21 24/2 24/5 29/3 29/18 33/10 33/25 35/8 40/4 40/6 45/18 45/24 48/3 48/20 51/8 54/16 57/23 58/4 58/6 58/10 58/20 59/18 60/13 60/19 66/4 66/5 66/21 66/25 67/17 68/18 69/5 69/6 69/10 69/15 71/12 71/22 72/25 77/17 78/3 79/7 80/4 82/3 83/17 86/23 90/16 91/21 93/1 93/4 94/8 94/10 94/18 95/7 96/18 97/20 100/14 102/14 105/11 105/20 111/23 116/4 117/9 119/2 123/15 124/6 124/13 124/18 124/18 125/20 127/13 131/7 132/7 133/18 137/8 138/9 139/1 140/17 141/4 141/10 145/1 145/14 148/16 149/13 149/13 153/3 155/22 159/2 159/24 160/5 160/21 160/23 161/5 161/14</p> <p>all theories [1] 94/8</p> <p>Allbright [5] 14/13 14/15 18/22 25/22 57/21</p> <p>allegation [22] 5/15 11/15 11/21 11/23 18/16 46/18 50/15 53/8 73/15 77/19 88/7 113/6 115/9 116/19 116/21 117/7 118/11 120/22 130/20 133/24 144/19 144/19</p> <p>allegations [24] 5/25 22/8 42/18 45/3 53/16 60/9 82/24 83/16 88/3 112/22 114/11 114/14 114/23 118/5 118/25</p>	<p>122/10 126/18 130/1 130/24 132/8 132/19 132/24 133/10 147/6</p> <p>allege [19] 5/7 6/1 19/13 36/17 36/19 46/5 48/23 50/17 63/1 68/6 68/8 68/11 92/20 116/6 117/13 126/14 127/13 143/17 154/19</p> <p>alleged [18] 11/17 24/7 34/13 49/1 53/14 53/19 57/25 70/4 72/11 83/8 83/12 83/23 85/18 87/12 102/11 118/15 127/22 128/18</p> <p>allegedly [4] 53/19 58/2 70/23 72/14</p> <p>alleging [4] 11/1 43/17 52/13 53/9</p> <p>alleviate [1] 19/24</p> <p>alleviates [1] 74/23</p> <p>allocate [1] 81/11</p> <p>allocated [1] 81/9</p> <p>allotment [1] 6/21</p> <p>allotted [5] 7/6 7/7 80/18 81/15 125/1</p> <p>allow [7] 36/17 62/1 65/25 71/20 87/2 117/23 159/6</p> <p>allowable [1] 117/18</p> <p>allowed [11] 46/22 70/19 70/20 70/21 101/19 112/25 122/3 123/8 137/25 138/5 141/22</p> <p>allowing [1] 30/9</p> <p>allows [2] 36/24 76/22</p> <p>almost [4] 23/20 71/25 96/11 147/24</p> <p>alone [1] 160/16</p> <p>along [5] 63/25 64/7 89/1 131/14 161/10</p> <p>already [14] 32/25 33/2 36/2 36/4 53/2 57/3 74/7 89/19 97/9 106/13 119/8 140/4 149/9 154/1</p> <p>also [53] 4/13 14/13 18/21 19/7 20/9 36/19 37/2 40/16 41/13 44/20 45/23 47/23 48/1 54/24 56/9 57/21 59/13 61/10 61/15 61/25 62/16 63/14 65/16 72/22 74/19 80/23 80/24 84/8 85/24 86/3 88/22 91/16 106/11 109/15 112/7 115/3 124/3 131/9 133/22 135/24 139/5 139/16 141/8 143/4 146/5 147/9 147/12 151/2 152/3 156/2 157/15 157/18 160/9</p> <p>alter [1] 111/15</p> <p>alteration [1] 96/6</p> <p>alternate [5] 12/23 13/18 13/24 14/2 14/10</p> <p>alternative [3] 50/9 58/5 135/9</p> <p>although [3] 66/8 77/9 87/9</p> <p>always [5] 6/22 13/11 36/18 51/4 91/10</p> <p>am [37] 3/18 4/17 5/13 7/14 8/4 8/10 10/3 17/11 25/9 37/6 40/1 48/17 60/11 66/7 66/21 67/14 73/14 74/4 87/2</p>
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<p>A</p> <p>am... [18] 107/11 110/7 118/16 124/2 124/3 125/25 125/25 129/6 136/22 136/23 137/17 138/1 145/15 148/10 148/23 156/8 157/10 159/15</p> <p>ambiguity [2] 35/15 136/19</p> <p>amenable [1] 81/11</p> <p>amendments [5] 15/2 16/15 90/14 131/10 131/11</p> <p>American [1] 100/3</p> <p>Americans [1] 24/2</p> <p>amicus [2] 24/20 108/21</p> <p>among [8] 37/12 65/2 81/20 82/10 82/23 105/23 115/2 148/17</p> <p>amount [4] 82/13 119/9 132/19 133/11</p> <p>amounts [2] 51/13 114/15</p> <p>amplify [1] 65/10</p> <p>analysis [33] 8/22 8/24 10/24 11/11 19/5 26/4 33/1 38/10 38/13 38/14 38/20 43/15 50/1 53/10 54/15 55/9 56/7 56/18 66/2 84/9 84/20 86/2 87/14 87/18 87/23 90/6 97/22 113/24 117/5 126/6 149/11 149/13 150/3</p> <p>analysis I [1] 56/18</p> <p>ANAND [2] 1/16 5/13</p> <p>anchor [5] 21/8 63/11 64/1 65/18 65/25</p> <p>ancient [1] 98/1</p> <p>and any [1] 118/1</p> <p>and implied [1] 72/21</p> <p>and investigate [1] 88/4</p> <p>and precautions [1] 139/3</p> <p>and prescription [1] 128/12</p> <p>and the [4] 48/25 72/15 112/17 150/19</p> <p>and then [1] 153/7</p> <p>and when [1] 131/20</p> <p>and/or [5] 41/13 47/24 61/16 84/5 161/3</p> <p>ANDA [16] 35/5 35/18 35/21 35/23 36/3 38/25 39/21 44/17 68/5 70/11 70/14 70/17 72/9 84/15 91/13 108/25</p> <p>ANDAs [1] 22/16</p> <p>ANDREW [8] 2/1 66/16 66/19 106/9 106/22 114/22 115/24 124/11</p> <p>Angeles [2] 1/20 1/24</p> <p>announce [1] 148/7</p> <p>announced [1] 34/18</p> <p>announcement [1] 103/21</p> <p>announces [2] 29/19 147/10</p> <p>annual [1] 23/23</p> <p>another [6] 4/13 12/15 58/24 79/8 110/8 112/4</p> <p>answer [18] 4/12 37/13 40/21 40/23 50/21 53/2 61/14 61/20 64/18 65/9 87/4 105/18 105/24 110/5 110/6 123/6 148/9 152/14</p> <p>answered [5] 60/2 60/2 60/11 106/13 110/11</p>	<p>answering [3] 66/6 122/18 122/22</p> <p>answers [1] 45/15</p> <p>antedating [1] 103/24</p> <p>anticipate [3] 7/19 94/9 121/21</p> <p>anticipated [1] 11/20</p> <p>antidote [2] 144/4 153/4</p> <p>any [120] 4/14 5/17 7/12 7/12 7/19 8/5 8/7 8/7 8/12 10/3 10/3 10/10 13/17 17/15 21/13 22/2 25/14 28/6 28/22 31/15 35/7 37/7 39/11 39/15 39/23 41/9 43/22 43/23 45/1 46/11 47/8 52/5 53/24 61/12 61/20 62/14 63/17 64/13 65/5 66/25 66/25 67/14 67/18 68/9 68/22 70/16 71/11 72/19 73/15 73/15 74/23 75/25 77/4 78/18 78/25 80/6 80/21 81/21 81/22 82/3 84/14 85/10 85/17 85/22 85/24 86/18 87/4 87/18 88/13 88/16 90/5 90/9 90/11 92/5 94/16 97/18 98/5 99/14 99/16 100/15 101/1 103/5 103/6 104/12 104/15 105/18 105/22 107/23 110/1 110/3 110/19 110/24 111/18 111/18 111/25 113/6 113/25 114/3 116/22 117/8 117/20 118/1 123/23 125/15 126/8 126/23 127/22 131/19 133/20 134/2 140/12 140/20 141/7 142/3 143/20 145/11 146/24 147/20 152/7 159/9</p> <p>any requirement [1] 88/16</p> <p>any Supreme [1] 10/3</p> <p>any written [1] 64/13</p> <p>anymore [2] 44/22 149/25</p> <p>anything [12] 23/1 25/14 51/14 70/18 84/10 90/18 94/5 97/6 97/21 117/8 137/12 160/19</p> <p>anywhere [4] 13/23 15/15 24/6 120/24</p> <p>apart [3] 79/14 79/14 145/2</p> <p>apologize [2] 38/3 156/12</p> <p>apparently [1] 86/2</p> <p>appear [4] 15/15 84/25 85/4 120/23</p> <p>appearance [2] 23/6 125/3</p> <p>appearing [1] 7/14</p> <p>appears [3] 71/4 135/15 135/23</p> <p>applicable [1] 90/11</p> <p>applicants [1] 22/15</p> <p>application [3] 12/16 15/13 35/21</p> <p>applications [1] 22/14</p> <p>applied [6] 11/11 72/13 84/13 101/11 101/20 103/23</p> <p>applies [15] 19/8 23/16 26/25 35/25 41/22 63/13 72/2 74/18 74/19 75/8 86/24 92/4 103/19 103/20 158/4</p> <p>apply [32] 6/11 10/22 18/6 23/14 27/17 29/22 33/20 35/22 51/10 64/3 68/16 68/19</p>	<p>72/18 74/17 75/23 76/9 79/21 103/17 104/9 105/11 105/15 112/13 122/9 124/13 127/25 136/8 146/19 147/25 153/23 157/18 157/19 159/10</p> <p>apply Mensing [1] 10/22</p> <p>apply principles [1] 29/22</p> <p>applying [1] 138/10</p> <p>appreciate [4] 4/5 6/15 124/19 153/10</p> <p>appreciative [1] 66/7</p> <p>approach [5] 13/23 17/17 19/7 100/22 141/25</p> <p>approaches [1] 14/3</p> <p>appropriate [6] 37/7 46/7 63/5 133/23 141/23 150/2</p> <p>appropriately [1] 118/21</p> <p>approval [11] 20/13 23/20 28/21 35/17 42/4 42/8 43/25 84/14 131/13 131/14 139/10</p> <p>approved [31] 21/21 22/13 23/19 28/21 29/1 29/7 38/24 64/25 78/12 101/18 112/8 112/10 113/7 113/12 115/10 126/12 127/13 128/7 128/9 130/13 130/14 130/15 132/21 134/17 135/18 144/20 151/15 151/18 156/18 156/21 157/2</p> <p>approves [1] 29/4</p> <p>approximately [2] 125/12 158/17</p> <p>April [1] 38/23</p> <p>April 2004 [1] 38/23</p> <p>aptly [1] 50/5</p> <p>are [324]</p> <p>are due [1] 108/24</p> <p>are obviously [1] 10/1</p> <p>are replete [1] 45/3</p> <p>are subject [1] 71/2</p> <p>areas [1] 82/17</p> <p>aren't [7] 19/19 33/3 43/7 44/9 64/24 94/15 113/19</p> <p>arena [1] 131/9</p> <p>argue [15] 21/23 24/24 39/20 51/19 60/5 62/18 64/15 66/21 73/13 73/22 74/13 77/9 117/25 122/6 122/8</p> <p>argued [3] 58/10 80/5 129/11</p> <p>argues [1] 62/11</p> <p>arguing [7] 24/25 30/6 56/6 58/25 67/12 79/19 126/2</p> <p>argument [44] 7/2 7/17 9/25 16/24 17/5 17/8 20/16 36/11 44/20 44/22 44/22 62/19 62/21 62/21 63/7 65/14 65/15 67/20 69/13 71/7 79/6 82/11 86/13 87/6 88/18 101/4 101/10 101/19 101/21 103/2 103/4 103/8 118/7 128/5 128/22 132/4 135/1 139/11 147/18 148/18 151/14 156/11 156/15 158/4</p> <p>arguments [36] 7/16 8/8 8/10 13/7 15/20 19/21 42/16 46/4 63/17 68/15 68/19 69/3 70/5 72/1 74/4 74/7 79/7 81/9 82/23 84/3 91/2 94/20 97/10 97/23 100/16 101/7 102/6</p>
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

A arguments... [9] 122/2 124/12 126/5 129/8 136/2 137/23 141/21 142/3 161/17 arisen [1] 104/7 arises [3] 15/10 15/11 18/3 arising [2] 103/24 105/13 Arizona [5] 33/7 33/8 33/12 33/14 77/20 Arkansas [1] 158/20 arm's [1] 5/22 armed [1] 158/19 Arnold [1] 1/16 arose [1] 51/24 around [8] 13/13 29/11 29/25 45/17 45/25 71/6 77/5 79/19 arrived [1] 100/11 Article [1] 25/15 articulated [2] 71/3 153/11 as [234] as innocent [1] 97/17 ascertain [3] 100/4 148/16 149/13 ASHLEY [34] 1/11 23/7 23/12 38/18 39/8 40/1 41/16 50/19 55/18 58/22 60/17 61/17 62/23 65/7 73/24 91/9 107/10 107/19 108/13 110/6 111/9 112/15 113/13 118/19 121/5 122/20 134/23 146/20 147/1 147/23 149/15 151/11 154/11 158/18 aside [2] 83/25 98/13 ask [11] 34/13 52/3 58/8 59/21 60/3 63/19 67/10 67/17 124/21 144/21 158/8 asked [4] 4/22 81/7 106/1 142/3 asking [7] 13/22 24/23 30/3 34/10 52/5 83/2 91/20 asks [1] 9/3 aspect [2] 102/8 126/8 assert [3] 128/11 128/21 132/25 asserting [2] 128/3 129/8 assertion [1] 133/17 asserts [1] 85/2 assistance [5] 34/13 36/10 42/5 52/4 91/16 associate [2] 7/15 125/9 associated [5] 85/3 96/19 136/18 147/10 149/21 assume [2] 19/16 109/14 assuming [2] 53/11 158/23 assured [1] 153/9 attempt [2] 104/19 150/24 attempted [1] 35/2 attempting [1] 86/21 attention [4] 29/17 30/20 36/14 113/9 attorneys [5] 4/1 76/12 80/14 105/21 161/5 audio [4] 7/9 15/23 37/9 80/9 audios [1] 66/8 authorities [1] 14/17 authority [4] 85/22 85/25	141/3 158/24 authorized [1] 89/3 automatically [1] 136/13 available [10] 6/15 74/15 93/25 94/8 94/15 94/18 95/2 95/14 138/18 139/9 Avenue [1] 2/2 avoid [7] 9/4 9/8 16/19 43/10 43/18 112/1 150/24 await [1] 78/24 aware [9] 51/1 73/14 107/7 107/12 110/1 123/23 124/2 124/3 148/10 away [9] 8/15 86/3 131/20 133/9 133/23 133/24 134/9 134/13 134/14 B back [25] 4/11 11/13 27/9 28/21 37/6 42/3 55/1 59/1 63/7 66/8 77/8 80/11 80/13 101/1 102/25 107/5 121/7 126/18 132/24 135/11 136/12 138/9 143/20 155/1 158/8 backed [3] 32/13 115/6 134/9 background [4] 4/19 15/24 25/11 116/25 bacon [1] 24/8 ball [1] 33/6 Baltimore [1] 2/14 banc [1] 32/22 bar [2] 13/5 104/15 barn [1] 152/7 Barnes [9] 1/22 2/5 2/12 7/14 15/21 21/2 34/20 36/2 36/12 barred [2] 11/9 25/6 bars [2] 69/5 127/9 Bartlett [70] 8/20 10/2 10/8 10/13 10/22 12/17 12/25 13/14 13/19 16/20 17/18 18/4 18/11 20/14 22/12 22/19 24/20 24/23 26/7 27/24 28/25 29/9 29/13 30/2 42/6 53/24 54/17 55/13 62/8 69/5 69/23 70/2 70/24 71/3 71/6 71/14 71/23 72/12 74/14 79/20 82/14 84/18 86/4 86/25 95/2 95/13 97/4 101/23 102/2 102/24 105/1 108/21 123/25 135/17 138/16 143/23 149/2 149/9 150/7 150/7 150/15 151/13 151/22 151/24 151/25 152/12 152/12 153/3 153/6 153/10 Bartlett embraced [1] 138/16 Bartlett was [1] 95/13 Bartlett what [1] 151/13 Basch [1] 32/22 base [3] 16/18 52/2 127/17 based [38] 8/18 16/4 18/9 22/5 27/6 29/23 34/12 37/17 37/19 40/24 53/12 53/16 55/9 57/24 63/22 69/15 70/9 70/10 78/1 94/16 99/24 100/21 102/6 106/6 114/6 115/17 117/22 119/7 121/1 128/3 128/5 137/23 143/25 145/19	148/18 153/5 155/18 159/3 basic [4] 14/2 72/2 92/18 113/24 basically [9] 11/10 11/24 12/8 14/8 18/3 83/12 84/2 87/1 138/16 basis [13] 24/3 63/24 64/8 72/20 72/22 85/7 111/8 117/9 117/11 118/11 121/24 129/9 157/20 basis for [1] 63/24 batch [4] 51/1 78/2 114/15 119/17 batches [6] 78/4 115/14 115/21 117/20 118/2 119/12 Bates [17] 26/16 26/20 27/2 36/21 41/22 48/13 48/14 92/8 95/5 104/21 104/24 105/1 105/2 105/3 138/10 148/2 148/5 Bates that [1] 104/21 be [189] be a [1] 157/25 be consistent [1] 41/1 be imposed [1] 92/6 be in [1] 26/10 BEACH [3] 1/2 1/5 2/18 bear [2] 33/1 136/9 bearing [1] 22/2 became [1] 23/21 because [112] 3/14 5/1 6/6 11/15 11/17 14/22 18/23 22/15 23/15 24/8 24/9 24/11 29/7 30/16 30/20 31/25 32/19 33/7 34/16 34/20 36/17 36/21 37/3 37/13 40/15 43/9 44/3 44/21 46/22 47/20 48/2 48/12 49/7 51/15 53/14 55/9 56/14 56/22 59/22 61/24 61/25 62/13 63/21 63/22 67/4 67/11 68/3 69/18 70/11 70/16 72/8 73/3 74/3 75/1 78/7 82/15 84/4 84/6 84/9 84/22 86/14 87/11 89/10 92/11 94/8 96/13 96/16 97/5 99/9 102/5 102/8 103/12 103/23 105/3 106/24 108/19 108/24 111/12 112/19 113/18 115/5 115/15 115/20 118/8 118/16 127/17 128/5 128/9 132/13 134/16 135/21 136/21 137/9 137/19 139/7 140/8 140/10 142/7 142/10 142/14 143/3 143/11 144/15 145/1 149/9 151/14 152/5 153/21 155/19 157/12 158/21 159/22 because state [1] 96/13 become [2] 13/22 124/10 becomes [1] 18/14 been [42] 3/3 7/6 7/7 10/15 10/18 12/21 13/6 17/14 17/16 18/19 21/21 36/20 37/3 39/16 51/25 57/3 57/17 58/7 63/1 78/12 83/3 86/23 92/17 98/7 110/10 110/15 116/7 119/8 126/15 126/20 130/20 132/6 133/1 135/2 138/9 142/3 144/2 150/3 160/24 161/2
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

B	121/14	bypass [1] 128/2
been... [2] 161/7 161/11	bound [1] 43/4	C
been rebuffed [1] 58/7	Bradley [1] 103/16	CA [2] 1/20 1/24
before [24] 1/9 3/20 31/16	branches [1] 143/6	California [14] 32/4 33/8
38/16 45/10 61/20 66/9 77/24	brand [24] 5/21 6/8 6/9 9/16	33/13 33/15 33/24 34/4 34/16
81/11 83/3 84/21 89/18 89/24	9/20 9/23 9/24 20/3 20/5	55/23 57/2 60/21 62/25 65/4
99/8 104/16 107/3 117/10	39/12 39/17 42/9 48/25 49/22	65/19 155/12
121/2 121/2 121/20 131/23	59/8 63/15 65/14 68/4 69/12	California's [1] 65/1
138/10 144/1 154/17	101/8 136/4 138/23 157/11	call [7] 32/17 71/8 71/10
began [1] 27/9	157/19	107/13 148/10 154/13 155/12
begin [7] 26/4 27/19 32/2	branded [10] 32/15 35/1	called [5] 10/6 35/10 83/19
34/22 67/23 105/25 135/2	35/12 125/8 126/2 128/9	97/12 142/14
beginning [2] 99/12 142/2	128/14 128/18 128/21 135/8	calls [1] 107/12
behalf [16] 7/14 66/21 67/12	branding [1] 127/19	came [7] 30/7 88/1 96/4
73/25 76/13 78/9 80/23 81/3	brands [9] 9/25 17/7 135/21	100/10 104/17 147/14 158/19
81/10 82/8 87/7 91/9 115/24	136/6 136/9 138/14 141/8	can [86] 4/3 6/22 12/18 20/7
125/8 126/2 127/4	154/24 155/3	22/16 23/8 23/9 25/4 26/23
behest [1] 97/12	brands' [2] 140/17 151/14	27/6 31/8 31/10 31/13 37/8
being [11] 12/12 15/7 49/10	breach [11] 20/25 21/9 27/7	37/22 39/2 39/11 39/15 44/11
51/21 52/14 52/21 60/7 83/18	27/7 71/10 71/11 72/4 97/18	47/2 50/23 53/21 54/5 55/16
84/3 92/20 118/15	100/15 100/16 154/20	58/11 59/2 59/12 63/19 63/23
being identical [1] 15/7	breached [5] 61/25 63/24	64/1 64/8 65/5 65/10 65/11
believe [13] 40/22 49/20	73/2 98/5 108/4	65/25 66/7 68/20 73/22 73/22
58/24 63/16 72/25 73/10	breaching [3] 61/24 123/9	75/17 76/20 77/4 81/19 81/21
81/10 113/14 113/25 125/11	123/10	91/24 92/3 92/7 93/11 96/12
134/7 146/22 147/16	breadth [1] 129/25	98/10 104/1 105/20 105/23
bellwether [1] 150/1	break [6] 47/6 59/22 66/10	111/23 113/4 113/9 115/17
below [1] 121/14	66/10 80/20 84/2	117/4 120/1 121/3 121/8
benefit [2] 4/20 49/14	breaks [2] 24/14 119/4	123/14 125/18 125/21 125/23
beside [1] 143/9	brief [14] 15/19 17/12 24/20	125/24 129/17 130/16 130/19
best [2] 23/21 159/3	34/22 35/2 36/11 73/25 101/4	133/12 135/18 136/8 136/22
better [7] 17/4 41/13 47/23	104/14 108/21 130/6 136/10	137/15 138/12 141/12 143/7
61/15 109/1 156/6 156/13	154/25 159/14	145/14 148/17 150/18 151/8
between [27] 4/4 15/9 27/1	brief the [1] 35/2	153/11 154/19 157/24 158/5
31/19 41/23 47/5 47/15 49/10	briefed [2] 17/6 143/6	160/16
49/11 52/23 56/11 65/22 67/5	briefing [14] 8/21 9/11 16/4	can't [34] 25/4 25/5 26/2
68/13 75/6 80/19 83/15	38/25 72/16 79/4 109/11	32/20 33/1 33/22 36/21 39/22
101/15 104/4 112/18 114/5	113/5 113/10 136/4 137/16	48/3 49/14 56/23 61/23 63/11
115/21 131/6 138/11 142/21	145/9 147/5 161/6	79/9 79/9 79/10 79/10 91/14
156/24 157/22	briefing on [1] 136/4	91/15 91/16 91/17 91/21 92/5
between pharmaceutical [1]	briefly [10] 20/1 48/22 54/2	94/3 94/18 111/24 112/13
68/13	57/10 71/24 79/2 79/5 101/4	116/11 117/13 119/16 137/24
beyond [2] 83/5 117/22	120/8 151/8	138/17 139/25 141/7
big [3] 23/18 137/10 140/25	briefs [10] 13/2 13/3 67/5	cancer [15] 19/19 24/15 41/9
billion [1] 23/23	67/7 72/5 82/16 85/22 105/8	42/10 43/11 44/10 45/11 47/7
binding [1] 149/17	131/8 147/14	59/10 61/11 62/3 76/16
Bird dog [1] 100/5	bright [1] 17/25	113/17 113/20 139/14
bit [8] 65/10 95/3 114/4	bring [4] 59/4 93/11 93/13	cancer-causing [1] 47/7
137/14 138/7 154/1 154/2	153/17	candid [3] 50/21 151/23
154/5	broad [8] 17/25 31/5 31/23	151/23
blockbuster [1] 23/22	86/2 129/13 133/20 142/18	candor [1] 122/1
Board [1] 103/17	142/20	cannot [19] 10/9 11/9 28/13
boils [1] 130/6	broader [2] 90/13 121/8	28/19 30/12 31/21 43/13
borne [1] 85/21	broadly [1] 10/22	68/20 69/25 70/3 84/12 89/8
borrowed [2] 30/18 30/24	brought [9] 22/18 58/13	102/9 126/24 134/16 135/12
both [42] 22/5 26/3 31/12	58/14 58/16 58/18 93/12	138/2 142/7 150/11
31/20 32/20 35/1 37/1 38/22	121/1 127/3 141/15	canon [1] 98/22
38/23 43/3 48/10 67/7 67/12	Buckman [3] 33/20 33/20	canons [1] 98/20
69/6 75/19 81/10 81/17 82/9	52/15	Canter [1] 131/7
84/1 88/12 88/23 91/3 91/24	build [1] 129/10	Cantor [2] 140/15 159/15
98/18 105/10 105/21 119/19	bulb [2] 96/2 96/3	capacity [1] 72/10
126/8 128/12 130/6 133/7	bulbs [1] 96/14	capitalized [2] 99/6 100/21
138/21 142/6 146/2 150/19	bunch [2] 30/18 137/22	capsule [2] 11/16 19/11
150/22 150/25 153/9 157/23	burden [5] 56/23 94/22 114/2	capture [2] 61/6 88/19
158/3 160/22 161/5	141/16 145/1	captures [1] 24/21
bother [1] 63/16	business [3] 5/3 5/16 5/23	card [1] 135/23
bottom [3] 16/17 117/7	but conscripting [1] 98/5	Cardinal [1] 66/19
	buy [2] 59/21 96/2	

<p>C</p> <p>care [5] 6/14 6/18 24/10 58/1 108/1</p> <p>careful [1] 161/5</p> <p>Carter [3] 131/6 140/15 159/15</p> <p>carve [5] 63/9 65/20 76/7 147/16 153/22</p> <p>carved [1] 140/13</p> <p>case [81] 1/3 3/15 9/18 12/11 12/21 13/1 13/8 13/16 13/17 14/5 14/7 14/13 17/1 17/2 19/10 19/23 21/25 21/25 24/17 26/25 27/6 30/2 31/17 41/5 43/11 44/1 48/11 48/18 49/21 49/21 49/22 49/25 53/4 54/24 54/25 55/24 56/1 56/10 57/7 57/23 62/25 64/25 67/16 75/11 85/23 103/24 109/23 110/2 112/22 113/4 113/14 113/23 113/25 123/16 131/7 131/7 131/7 132/1 132/5 132/13 140/15 141/5 141/6 141/9 142/12 142/13 144/2 144/14 145/10 146/19 151/4 152/3 152/11 152/11 152/12 153/8 159/9 159/20 159/22 161/10 161/12</p> <p>case that [1] 55/24</p> <p>case where [1] 159/9</p> <p>cases [44] 15/19 16/4 16/5 16/18 16/21 18/17 18/19 26/6 30/19 30/22 32/21 48/16 49/18 49/19 49/21 51/23 53/25 53/25 54/11 54/22 56/20 57/6 57/11 57/12 57/13 57/23 70/8 70/25 76/4 92/8 131/5 132/10 140/16 140/17 140/17 140/22 140/25 142/10 152/2 159/13 159/13 159/14 159/14 159/17</p> <p>cast [1] 98/13</p> <p>catch [1] 108/4</p> <p>catchall [1] 131/19</p> <p>categories [5] 25/17 75/6 94/3 135/25 143/13</p> <p>categories of [1] 143/13</p> <p>category [8] 4/25 25/19 29/10 30/16 74/10 75/1 142/3 145/10</p> <p>category there [1] 25/19</p> <p>caught [1] 108/2</p> <p>causation [10] 27/12 54/19 54/20 56/6 56/12 56/14 56/21 56/23 57/6 102/15</p> <p>cause [29] 14/11 17/19 18/4 19/21 26/18 27/4 45/11 53/12 58/13 58/14 58/16 59/2 59/13 59/15 59/19 71/19 79/16 95/12 107/8 107/12 109/15 117/5 118/24 133/12 133/19 133/20 147/25 148/4 148/10</p> <p>caused [4] 30/7 61/11 96/9 114/19</p> <p>causes [20] 11/8 12/8 12/20 24/15 41/9 57/15 59/1 59/6 59/23 62/3 76/3 76/9 85/2</p>	<p>95/7 147/21 148/11 148/13 148/14 148/14 149/16</p> <p>causing [3] 47/7 113/17 113/20</p> <p>caveat [1] 154/17</p> <p>CBE [2] 36/6 139/8</p> <p>ceasing [1] 10/11</p> <p>ceiling [1] 157/15</p> <p>Celsius [2] 49/11 49/12</p> <p>centerpiece [1] 103/8</p> <p>Century [1] 1/23</p> <p>certain [7] 52/25 60/13 94/11 94/16 94/24 110/16 131/14</p> <p>certainly [8] 3/13 57/7 60/24 90/23 108/2 132/12 139/6 156/17</p> <p>certify [1] 162/1</p> <p>certitude [1] 13/8</p> <p>CFR [6] 20/11 29/3 35/11 35/23 43/22 135/17</p> <p>chain [20] 67/6 68/1 68/15 69/14 74/17 83/6 84/24 87/3 87/8 98/15 103/21 110/10 110/13 110/23 110/25 122/6 122/7 122/13 122/19 122/23</p> <p>chains [1] 82/24</p> <p>challenge [11] 18/12 31/15 31/15 31/21 43/1 132/19 142/2 142/7 142/16 155/23 156/21</p> <p>challenges [4] 84/23 128/25 144/20 156/18</p> <p>chance [1] 97/1</p> <p>change [46] 9/25 10/4 20/9 20/10 20/12 36/4 36/5 37/2 37/3 42/7 43/12 43/22 43/23 43/24 43/25 44/3 44/4 46/18 46/25 53/23 59/9 70/14 70/19 70/20 70/21 72/10 79/9 79/9 79/10 79/11 84/16 91/16 92/2 92/6 92/7 94/5 114/4 116/11 127/18 139/10 139/13 139/20 139/24 157/12 157/14 157/20</p> <p>change because [1] 157/12</p> <p>changed [11] 12/2 12/3 34/21 35/16 36/25 42/8 66/3 84/25 139/3 139/6 139/7</p> <p>changes [10] 22/16 35/7 35/19 36/3 38/24 42/7 46/23 70/16 114/3 156/24</p> <p>changing [4] 11/2 34/14 36/22 46/15</p> <p>characterize [2] 97/17 160/6</p> <p>characterized [1] 160/7</p> <p>characterizes [1] 145/4</p> <p>chase [1] 100/5</p> <p>Cheffo [1] 4/22</p> <p>chemical [1] 129/1</p> <p>chemistry [1] 11/17</p> <p>Chicago [1] 1/13</p> <p>Chief [1] 33/21</p> <p>choice [4] 47/21 93/17 96/23 150/3</p> <p>choices [2] 92/21 98/11</p> <p>choices that [1] 92/21</p> <p>choose [2] 39/19 93/10</p> <p>chosen [1] 97/24</p>	<p>circle [1] 4/11</p> <p>Circuit [18] 10/18 17/20 18/20 18/21 26/22 44/1 49/3 50/2 50/3 52/16 52/18 53/6 54/24 54/25 57/20 57/20 98/21 152/3</p> <p>Circuit's [4] 11/6 32/21 33/11 48/15</p> <p>circumstances [6] 11/20 33/17 47/18 52/25 130/20 152/6</p> <p>circumvent [1] 58/6</p> <p>citation [2] 52/5 159/9</p> <p>citations [1] 142/9</p> <p>cite [16] 21/25 33/10 33/14 39/22 45/4 62/25 72/15 75/21 85/23 85/24 103/25 116/17 140/15 141/9 141/9 146/11</p> <p>cited [16] 16/3 30/19 33/15 38/23 49/22 70/25 75/11 85/22 104/13 105/8 113/4 114/1 131/7 140/23 146/5 159/14</p> <p>cites [1] 117/1</p> <p>citing [1] 104/20</p> <p>citizen [3] 5/1 5/12 6/4</p> <p>civil [9] 25/6 65/4 76/1 76/11 76/15 76/19 76/22 77/3 112/1</p> <p>claim [94] 9/8 10/3 12/13 16/25 17/4 19/25 20/22 20/23 20/25 21/8 21/10 21/24 21/24 37/19 44/2 50/9 51/20 52/13 52/15 52/20 52/22 54/18 55/1 55/12 59/8 63/11 64/6 64/9 65/5 65/19 65/23 65/24 66/1 70/4 71/15 71/20 72/3 72/4 72/20 72/23 78/7 85/15 87/23 93/25 101/10 101/23 102/9 102/10 102/14 105/2 105/3 113/6 116/7 116/9 117/10 117/12 118/7 123/24 126/8 128/3 128/23 129/15 130/6 131/18 133/6 133/11 133/13 133/19 134/9 138/5 138/12 138/17 138/25 140/18 141/2 141/11 141/14 141/18 144/16 144/17 145/5 145/7 154/4 154/9 154/9 154/14 155/12 156/4 156/16 160/6 160/8 160/16 160/18 160/19</p> <p>claim merely [1] 128/23</p> <p>claiming [3] 20/8 103/1 128/3</p> <p>claims [146] 8/11 9/5 10/16 11/1 11/24 12/18 13/25 14/20 15/12 16/2 18/18 21/3 21/5 21/20 21/20 22/5 22/10 22/18 22/20 26/23 30/13 30/17 30/23 31/25 33/1 33/3 34/12 34/15 52/3 57/24 58/19 59/4 60/3 60/6 60/10 60/22 61/6 62/13 63/6 63/13 63/14 63/16 63/22 64/16 64/21 64/23 64/24 65/25 68/17 68/24 69/5 69/10 69/15 69/17 69/19 69/20 70/9 70/10 70/22 71/22 71/25 72/6 72/7 72/11 72/14</p>
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<p>C</p> <p>claims... [81] 73/6 73/9 73/14 77/8 78/19 83/11 84/2 84/8 84/19 85/4 85/19 86/6 86/12 87/15 89/10 89/13 89/16 90/4 93/10 95/10 100/6 103/13 103/20 104/6 105/11 105/13 122/8 124/6 124/13 126/3 126/24 126/25 127/4 127/7 127/10 127/14 127/17 127/20 127/24 128/12 128/14 128/17 128/24 129/14 130/4 130/9 131/22 133/5 133/24 134/2 134/10 136/8 137/18 138/3 140/1 140/11 141/15 142/5 143/9 144/13 144/16 144/21 145/5 145/6 145/6 145/6 145/10 149/9 149/14 153/14 153/17 153/21 154/19 154/21 154/25 155/3 155/5 155/7 155/18 155/23 157/9</p> <p>claims against [1] 68/17</p> <p>claims are [1] 11/24</p> <p>claims insist [1] 89/16</p> <p>clarification [1] 122/21</p> <p>clarify [2] 129/10 136/20</p> <p>class [15] 22/8 69/2 69/18 72/24 88/2 124/14 127/5 128/13 129/14 130/3 131/22 132/18 141/15 146/7 146/8</p> <p>clause [46] 10/23 14/20 15/2 15/14 15/15 16/12 18/14 25/16 31/4 31/23 33/17 76/2 88/12 88/12 88/18 99/6 99/11 100/17 100/18 100/19 100/21 103/1 104/17 123/1 123/2 127/22 137/24 138/20 138/21 139/12 139/13 140/7 140/10 140/13 140/19 141/13 142/18 144/24 145/2 154/13 154/18 154/22 155/8 155/9 158/4 160/1</p> <p>clauses [3] 142/20 142/23 143/1</p> <p>clear [27] 9/11 12/16 16/20 22/4 25/7 29/14 42/18 42/22 43/2 43/11 43/12 55/3 70/8 104/9 104/11 104/11 104/14 105/11 107/11 131/21 139/20 145/16 146/16 156/2 156/10 156/14 157/1</p> <p>clearer [1] 100/19</p> <p>clearly [5] 18/8 34/24 92/19 104/6 116/4</p> <p>close [1] 152/21</p> <p>closer [1] 54/7</p> <p>Coca [1] 85/11</p> <p>Coca-Cola [1] 85/11</p> <p>Code [4] 29/2 32/14 65/4 135/10</p> <p>Code Section [1] 65/4</p> <p>codes [1] 76/13</p> <p>Cola [1] 85/11</p> <p>colder [2] 121/12 121/13</p> <p>Coleman [3] 32/5 55/24 60/21</p> <p>Colgate [1] 105/9</p> <p>colleague [4] 74/5 80/24</p>	<p>87/11 126/1</p> <p>come [16] 7/23 23/4 31/17 37/6 37/9 60/24 67/18 73/22 73/22 101/1 105/21 124/21 135/8 143/20 145/15 157/13</p> <p>comes [9] 44/24 49/14 63/25 64/7 75/21 99/3 132/16 135/20 139/17</p> <p>coming [5] 60/4 63/7 66/8 121/7 124/23</p> <p>commend [2] 55/23 56/9</p> <p>commerce [5] 28/14 75/24 77/3 111/20 112/3</p> <p>committed [1] 30/16</p> <p>Committee [1] 52/16</p> <p>common [15] 26/14 32/7 33/9 34/4 34/18 83/14 90/19 91/11 104/20 104/24 105/6 148/7 149/3 159/8 159/10</p> <p>commonplace [1] 95/25</p> <p>communicate [3] 52/11 53/4 57/25</p> <p>companies [2] 5/19 68/23</p> <p>Company [1] 109/20</p> <p>comparable [1] 20/4</p> <p>comparatively [1] 51/6</p> <p>compare [1] 28/3</p> <p>compared [1] 131/17</p> <p>compares [1] 126/7</p> <p>comparing [7] 26/4 27/10 27/19 32/2 34/23 76/5 131/4</p> <p>comparison [1] 129/20</p> <p>compelled [1] 108/9</p> <p>compels [1] 87/15</p> <p>compensate [2] 102/18 102/19</p> <p>compensation [4] 70/7 102/14 109/16 109/17</p> <p>complaint [50] 4/24 5/17 10/25 11/20 12/20 22/7 22/7 45/6 46/7 69/2 69/3 69/18 72/25 77/12 83/21 85/2 92/19 93/16 94/7 94/14 113/10 114/9 114/23 116/2 116/5 116/13 117/10 118/8 118/10 119/2 120/6 120/13 120/15 120/20 120/23 121/2 121/2 121/23 123/24 124/14 124/14 126/19 130/3 130/4 144/19 146/6 146/7 146/8 147/6 149/22</p> <p>complaints [28] 11/13 22/4 22/9 23/19 24/7 26/19 42/22 45/3 46/10 46/19 60/9 63/1 69/7 73/15 82/23 83/9 84/1 85/1 121/20 124/24 126/14 127/13 128/13 133/20 137/5 141/15 146/1 146/3</p> <p>complaints allege [1] 127/13</p> <p>complaints' [1] 88/2</p> <p>completely [7] 44/16 55/9 63/10 65/17 86/14 92/13 139/24</p> <p>complex [4] 140/25 141/5 141/8 141/24</p> <p>compliance [2] 62/1 144/3</p> <p>complied [5] 48/10 108/5 135/11 135/22 155/6</p> <p>complies [2] 128/7 130/13</p>	<p>comply [28] 4/6 10/10 25/24 26/3 27/5 32/20 33/4 38/20 40/16 47/20 48/3 59/12 70/1 89/5 91/17 91/21 92/5 92/7 93/4 93/22 101/24 112/23 118/18 120/6 128/18 142/6 150/11 150/19</p> <p>complying [5] 40/17 41/21 48/4 91/23 136/11</p> <p>component [1] 134/8</p> <p>composition [2] 129/1 130/14</p> <p>compound [3] 24/15 113/17 113/21</p> <p>con [1] 73/4</p> <p>concede [9] 85/14 85/18 86/11 91/12 92/5 94/3 94/4 154/6 154/12</p> <p>conceded [4] 9/21 9/24 35/3 155/18</p> <p>conceding [3] 156/3 156/16 156/17</p> <p>concept [9] 15/12 16/2 16/24 30/18 30/23 55/6 121/6 153/5 153/6</p> <p>concern [3] 34/11 34/16 52/7</p> <p>concerning [1] 42/17</p> <p>concession [2] 94/16 155/23</p> <p>conclude [4] 142/1 145/12 160/23 161/18</p> <p>concluded [3] 98/15 105/12 161/21</p> <p>concludes [4] 66/5 79/24 124/19 160/21</p> <p>conclusion [4] 34/19 87/15 92/11 151/3</p> <p>conclusive [1] 132/3</p> <p>conclusory [1] 118/23</p> <p>concrete [2] 31/17 142/4</p> <p>concurrence [1] 56/10</p> <p>condition [2] 44/8 73/3</p> <p>conditioned [1] 77/25</p> <p>conditions [28] 20/4 45/13 46/2 46/5 46/8 46/12 46/15 50/16 51/9 68/7 77/14 78/7 78/14 78/15 112/8 112/11 113/8 113/12 113/18 114/11 115/5 115/11 115/22 116/11 118/14 118/18 119/15 120/25</p> <p>conduct [4] 18/25 103/24 104/2 141/23</p> <p>conducted [4] 116/13 118/17 119/8 149/16</p> <p>conference [1] 161/16</p> <p>confident [1] 136/22</p> <p>confirm [5] 76/19 77/18 106/5 107/6 114/24</p> <p>confirmed [2] 77/13 103/16</p> <p>confirming [1] 90/22</p> <p>confirms [2] 25/2 116/14</p> <p>conflates [1] 71/8</p> <p>conflict [10] 4/14 25/12 26/5 26/24 42/12 50/7 52/23 53/22 79/12 148/20</p> <p>conflict exists [1] 53/22</p> <p>conflicting [3] 15/17 104/16 105/15</p> <p>conflicts [2] 10/5 22/18</p> <p>conforms [1] 65/3</p>
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--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>C</p> <p>confuses [1] 76/4</p> <p>Congress [13] 14/24 15/11 25/9 89/21 90/1 101/14 104/3 104/5 104/7 104/11 123/4 136/17 159/25</p> <p>Congressional [1] 105/11</p> <p>conjecture [2] 117/21 119/5</p> <p>conjunction [1] 80/19</p> <p>connection [1] 136/9</p> <p>conscripting [1] 98/5</p> <p>consequence [4] 91/14 98/19 112/25 139/25</p> <p>consequences [1] 149/7</p> <p>consider [1] 39/3</p> <p>considerations [1] 108/24</p> <p>considered [8] 13/6 17/24 21/18 30/5 87/9 126/21 152/10 160/4</p> <p>consistent [13] 26/11 37/1 41/1 44/16 48/4 62/7 105/6 136/14 137/20 142/16 142/17 143/2 161/11</p> <p>consistently [1] 48/10</p> <p>consolidated [2] 146/7 146/8</p> <p>constitute [3] 46/18 46/24 160/16</p> <p>constitute a [1] 46/24</p> <p>constitutes [1] 156/25</p> <p>constitution [2] 25/13 25/14</p> <p>construe [1] 14/24</p> <p>construed [2] 15/7 98/18</p> <p>consumer [20] 18/24 32/10 43/10 46/17 53/15 54/13 54/16 54/23 55/11 69/2 69/18 72/24 88/2 124/14 128/13 129/14 130/4 131/22 132/18 146/7</p> <p>consumer class [1] 132/18</p> <p>consumers [11] 44/9 51/21 52/2 52/21 56/4 60/7 68/10 78/16 97/1 127/9 153/16</p> <p>consumers from [1] 97/1</p> <p>consumption [1] 24/1</p> <p>contact [1] 68/10</p> <p>contain [1] 112/8</p> <p>contained [10] 28/12 75/14 75/14 77/15 119/19 120/1 121/17 123/11 147/16 147/17</p> <p>container [1] 44/3</p> <p>containers [1] 73/5</p> <p>containing [8] 51/2 51/5 51/12 100/9 111/11 112/25 114/16 119/13</p> <p>contains [3] 46/4 113/20 153/21</p> <p>contend [5] 113/11 116/18 153/14 153/20 159/5</p> <p>contend that [1] 159/5</p> <p>contends [1] 117/15</p> <p>content [3] 21/14 62/15 64/14</p> <p>context [15] 14/19 14/19 15/9 18/6 18/7 42/3 51/24 83/4 92/1 92/13 95/25 103/16 111/22 134/14 140/24</p> <p>contexts [2] 97/9 159/17</p>	<p>continue [9] 99/14 104/12 104/12 104/15 104/18 105/8 105/10 105/15 133/12</p> <p>continues [1] 19/15</p> <p>continuing [2] 13/9 49/18</p> <p>contradict [1] 136/6</p> <p>contradicted [1] 88/2</p> <p>contradiction [1] 128/6</p> <p>contrary [8] 16/4 19/20 25/15 85/25 88/18 99/4 116/6 137/13</p> <p>contrast [1] 144/18</p> <p>contravenes [1] 153/8</p> <p>control [4] 8/13 8/14 93/16 101/15</p> <p>controlled [2] 49/8 72/18</p> <p>conveyed [1] 79/3</p> <p>conviction [1] 75/13</p> <p>cool [3] 116/8 117/25 120/17</p> <p>core [5] 11/1 11/21 11/23 53/8 63/7</p> <p>corollaries [1] 26/8</p> <p>correct [21] 5/15 5/17 6/1 6/5 10/1 37/16 37/18 43/9 44/8 48/6 61/5 75/2 95/9 106/8 106/10 115/12 126/6 136/15 145/18 157/19 162/1</p> <p>corrected [1] 4/3</p> <p>correctly [4] 107/6 117/17 122/25 128/8</p> <p>corresponding [1] 26/13</p> <p>Cosmetic [4] 69/9 69/22 127/7 135/6</p> <p>could [78] 7/8 9/25 16/14 19/9 22/17 23/4 34/9 35/5 36/13 36/16 36/20 36/25 38/3 40/4 41/4 41/5 42/5 42/8 42/9 43/16 43/19 44/7 46/16 46/22 47/11 48/9 54/2 57/6 58/12 59/12 60/24 63/5 64/4 65/15 66/3 66/14 70/6 70/7 72/19 73/11 79/16 80/14 81/8 84/10 91/6 92/2 92/21 92/23 92/24 92/25 93/4 101/24 106/25 108/1 108/3 108/5 108/7 117/21 118/2 121/11 125/3 125/11 133/19 138/4 139/3 139/5 139/6 142/23 143/25 144/12 146/18 149/8 155/5 156/9 157/9 158/20 160/3 160/7</p> <p>couldn't [8] 24/19 35/3 35/6 37/2 45/1 64/6 65/18 92/2</p> <p>counsel [24] 4/2 7/8 9/12 23/1 23/5 37/14 62/16 66/5 66/14 66/14 67/17 67/20 69/23 79/4 80/4 80/17 80/19 82/12 101/7 101/8 124/21 125/3 145/14 146/2</p> <p>count [5] 10/17 49/20 61/2 61/3 69/18</p> <p>counter [9] 21/22 92/15 127/6 127/8 127/11 128/12 135/1 138/19 153/15</p> <p>counterparts [2] 32/15 78/6</p> <p>countless [2] 48/16 129/6</p> <p>country [4] 13/5 13/23 22/22 127/16</p>	<p>counts [8] 19/20 60/13 60/13 60/19 60/25 61/1 61/5 69/6</p> <p>couple [7] 3/5 45/4 62/23 107/2 131/25 134/18 155/17</p> <p>coupled [2] 119/11 137/4</p> <p>course [19] 3/11 21/15 38/18 63/14 68/9 77/10 78/8 84/25 93/14 96/9 112/21 118/23 121/25 133/22 133/23 138/20 139/1 141/23 159/1</p> <p>court [160] 1/1 2/17 3/9 4/1 6/7 7/1 7/11 8/16 8/18 8/21 8/25 9/3 9/8 10/2 10/3 10/8 10/15 10/18 13/16 13/20 13/22 14/3 14/17 16/6 16/6 16/7 16/21 17/15 17/18 18/2 18/19 18/21 19/10 19/24 22/22 23/12 24/23 25/21 26/6 26/15 27/15 27/23 28/24 29/13 29/16 29/19 29/20 30/20 31/16 33/7 33/22 34/9 39/2 39/11 39/16 42/25 44/2 44/4 50/2 50/4 50/5 51/22 52/4 52/19 53/3 53/6 55/2 55/5 55/23 56/9 57/21 57/22 57/22 58/10 58/11 58/20 62/9 63/21 66/11 67/25 68/22 70/8 70/8 71/6 71/7 71/14 71/16 71/17 75/10 76/10 80/6 80/19 81/10 82/12 84/21 85/9 86/18 87/8 93/14 95/4 95/13 97/4 98/18 98/19 98/21 99/9 100/22 103/16 103/17 103/18 103/19 104/24 105/7 105/12 113/4 114/8 118/6 118/9 122/1 124/12 126/20 126/23 127/25 128/6 128/24 130/18 131/2 131/2 133/8 133/14 134/13 135/16 136/15 142/13 143/11 144/12 146/16 148/2 148/5 148/24 149/2 149/17 151/2 151/23 151/24 152/6 152/13 152/17 155/24 155/25 156/20 158/12 159/3 159/8 159/9 160/24 161/6 161/8 161/15 162/6</p> <p>Court confirmed [1] 103/16</p> <p>Court precedent [1] 105/7</p> <p>Court to [1] 156/20</p> <p>Court's [12] 29/9 29/25 48/14 50/10 53/1 56/7 66/6 69/4 74/14 128/16 153/8 161/12</p> <p>courts [36] 10/21 11/5 11/10 12/17 13/4 13/10 13/11 14/24 15/5 16/1 16/11 17/16 17/23 19/6 21/18 22/21 26/4 29/22 34/18 46/20 49/2 49/24 54/14 54/21 58/4 70/22 70/25 72/13 87/9 98/25 127/16 131/10 137/17 138/2 144/6 159/16</p> <p>Courts' [1] 53/25</p> <p>covered [5] 36/2 69/12 69/24 79/6 134/7</p> <p>crafted [1] 64/19</p> <p>create [4] 16/12 26/23 86/21 132/11</p> <p>created [11] 13/12 28/4</p>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

C created... [9] 28/11 75/3 75/7 111/16 112/20 135/6 140/5 147/24 148/11 created by [1] 28/11 creates [4] 17/24 19/14 27/4 75/16 creating [1] 77/21 creative [4] 86/8 86/9 86/9 86/22 creature [2] 14/23 17/13 credit [2] 118/23 118/25 credits [1] 118/6 crime [1] 130/12 criminal [9] 75/12 75/13 75/16 75/18 76/15 101/13 111/22 144/9 147/17 criteria [2] 110/13 110/19 cross [3] 22/24 136/2 149/25 cross-cutting [1] 149/25 Crowell [1] 2/1 crucial [2] 99/20 99/23 crucially [1] 147/11 crystal [3] 29/14 139/20 145/16 current [1] 118/7 customary [1] 93/9 cutting [1] 149/25	deadlines [1] 161/11 deadly [1] 24/15 deal [1] 137/10 dealing [2] 78/12 149/24 deals [1] 15/15 dealt [2] 14/9 104/1 debriefing [1] 97/14 decades [1] 24/3 December [2] 1/5 162/4 decide [5] 29/23 62/9 105/23 125/18 152/5 decided [6] 10/13 10/14 86/8 93/6 93/7 151/2 deciding [1] 29/14 decision [21] 11/6 18/4 22/22 29/9 29/11 30/1 32/22 33/11 48/14 48/15 50/4 53/7 56/7 57/20 63/20 71/7 72/15 72/15 103/18 104/22 144/18 decisions [7] 8/18 10/16 10/18 10/21 13/14 21/21 79/20 decisis [1] 29/22 declined [3] 13/10 17/16 71/16 deemed [1] 151/5 deep [1] 84/24 defeat [1] 141/14 defect [39] 18/6 18/6 18/9 19/15 20/6 20/7 27/20 27/24 27/25 59/5 59/6 70/9 83/8 83/12 85/15 85/18 93/1 102/16 105/2 110/22 128/12 128/23 129/15 134/8 134/9 134/14 138/12 138/17 140/6 148/14 148/25 149/4 149/6 149/10 149/13 149/16 149/20 151/5 151/7 defective [13] 11/17 70/23 73/4 84/4 102/7 102/10 102/11 102/17 107/17 107/24 108/2 109/24 138/13 defectively [5] 27/21 28/1 140/3 149/1 149/5 defectiveness [1] 102/9 defects [7] 19/2 46/21 58/1 72/12 85/10 87/12 148/1 Defendant [25] 4/24 5/4 29/10 30/8 31/16 43/17 46/11 48/2 50/15 53/9 53/18 53/19 53/21 58/12 62/11 69/25 70/3 70/6 70/6 75/1 79/1 113/6 116/22 125/9 142/4 Defendant's [1] 53/13 defendants [102] 1/15 5/1 5/7 7/6 7/8 7/9 10/9 12/1 23/16 24/9 25/23 26/17 28/17 28/19 30/14 30/25 32/24 33/19 35/2 37/12 39/4 39/5 43/2 43/9 46/7 48/20 48/24 49/5 50/18 50/22 51/19 51/23 54/2 56/21 63/18 67/12 68/4 68/5 71/1 73/2 74/10 75/6 76/14 80/23 80/25 81/4 81/5 81/10 81/14 82/8 82/18 82/20 83/3 83/11 83/17 83/17 83/19 83/22 84/8 84/9 85/16 85/20 86/12 86/15 93/1 93/18 94/3	94/17 101/1 101/6 101/16 101/21 106/2 106/8 106/10 106/15 106/19 114/21 115/25 116/22 120/12 123/24 123/25 124/5 124/12 124/23 125/2 125/7 126/2 126/16 126/20 128/15 128/18 129/17 135/25 137/1 137/9 140/15 140/23 143/19 153/13 159/5 Defendants' [6] 66/11 80/15 124/9 124/23 128/22 145/17 defending [1] 126/13 defense [17] 25/23 37/9 37/14 37/15 37/17 37/22 38/2 38/8 38/23 62/16 66/14 66/17 94/9 114/2 121/21 129/13 145/19 defenses [3] 94/20 106/6 121/22 defer [3] 67/14 101/6 105/22 define [4] 99/23 141/14 141/18 159/24 defined [4] 99/5 100/1 159/25 160/19 defines [5] 23/22 65/1 88/9 100/1 100/3 defining [3] 89/20 146/4 159/3 definitely [2] 65/10 147/9 definition [22] 25/3 28/5 28/10 74/13 79/12 88/22 99/24 108/20 109/7 128/8 135/5 136/17 137/5 141/1 141/4 141/11 146/21 147/2 147/11 154/23 155/11 160/1 definitions [1] 140/5 degrade [4] 11/19 11/25 19/12 20/8 degrade the [1] 11/25 degree [1] 112/19 degrees [11] 47/5 47/7 47/9 47/17 49/10 49/11 112/7 112/9 112/11 112/11 114/5 deliver [1] 28/13 delivered [1] 96/14 demand [1] 126/21 demanding [2] 52/10 53/3 demanding [1] 25/23 demonstrate [7] 25/10 27/18 44/17 45/6 77/8 101/14 143/8 demonstrated [2] 33/2 35/9 demonstrates [1] 139/18 denied [1] 34/12 deny [1] 68/22 depart [1] 129/24 departs [1] 134/11 departure [2] 126/12 132/25 departures [3] 130/14 130/15 130/16 depend [2] 50/7 71/9 depositions [1] 119/24 Depot [7] 96/3 96/5 96/6 96/12 96/14 96/16 96/21 depth [1] 105/2 depth explaining [1] 105/2 derivative [2] 144/7 144/8 derivatively [1] 68/19 derived [3] 16/25 72/22
D D.C [1] 2/2 daily [1] 24/3 damage [1] 127/23 damages [4] 76/16 127/5 153/24 155/10 danger [1] 132/6 dangerous [14] 12/5 19/22 28/8 29/2 30/9 36/18 44/25 45/9 45/22 74/12 78/17 130/8 132/3 151/19 Dann [1] 2/13 Darvocet [6] 17/20 18/2 18/11 49/3 152/4 152/11 Datareich [1] 75/10 date [40] 19/10 19/13 19/14 19/17 19/23 34/20 34/25 35/4 35/16 36/5 36/9 36/25 39/12 39/17 39/19 39/22 39/24 40/6 40/7 40/11 40/12 40/18 40/20 40/24 41/2 41/10 42/9 42/19 42/20 43/10 44/8 44/10 44/19 59/16 92/2 92/23 93/7 93/13 105/14 162/4 dates [18] 23/15 35/14 35/25 36/14 36/19 41/20 42/17 43/8 45/2 45/4 45/7 45/23 58/15 59/14 64/3 79/11 92/1 139/6 dating [1] 35/15 day [9] 3/2 25/7 35/5 68/18 80/3 86/23 133/17 160/23 161/20 day that [1] 25/7 day when [1] 35/5 daylight [1] 31/19 days [4] 82/13 160/25 161/2 161/4 de [1] 29/23		

<p>D</p> <p>derived... [1] 145/7</p> <p>derived from [1] 72/22</p> <p>described [3] 23/19 56/15 144/7</p> <p>describing [1] 56/11</p> <p>desert [1] 77/20</p> <p>design [52] 9/17 11/2 11/18 12/2 12/12 18/6 18/6 18/9 20/7 27/20 27/23 27/25 59/5 59/6 68/2 70/9 70/14 70/20 72/11 79/10 84/11 84/16 85/3 85/13 93/1 95/22 101/15 105/2 128/11 128/23 128/25 129/15 130/15 134/8 134/9 134/14 134/17 138/12 138/17 140/6 144/20 148/1 148/14 148/25 149/3 149/6 149/10 149/13 149/16 149/20 151/5 151/7</p> <p>designed [8] 27/22 28/1 68/23 128/15 140/3 149/1 149/5 151/4</p> <p>Despite [2] 42/20 83/14</p> <p>detect [1] 85/10</p> <p>determination [2] 62/5 79/14</p> <p>determinations [1] 30/4</p> <p>determine [2] 140/18 159/6</p> <p>determined [1] 44/7</p> <p>determining [1] 85/18</p> <p>determining the [1] 85/18</p> <p>devastating [1] 25/1</p> <p>deviate [1] 117/25</p> <p>deviation [2] 9/19 116/19</p> <p>device [17] 14/19 15/1 15/5 16/5 16/15 16/16 30/19 30/24 31/4 31/24 49/20 51/24 57/12 90/14 131/10 131/11 142/19</p> <p>devices [3] 15/8 17/1 131/13</p> <p>DeVries [1] 2/13</p> <p>diagnose [1] 68/6</p> <p>dicta [2] 29/16 29/20</p> <p>Dictionary [1] 100/3</p> <p>did [49] 8/1 8/12 9/4 17/18 22/13 36/12 48/13 50/17 50/18 52/2 52/10 55/4 55/4 55/25 58/5 61/22 70/11 74/6 77/23 81/14 89/3 89/9 90/3 90/22 96/18 96/25 100/14 101/1 101/9 103/10 103/10 104/7 105/3 107/6 107/17 109/18 113/11 115/9 115/10 115/23 116/23 117/8 119/25 122/15 143/7 143/19 150/7 153/6 158/10</p> <p>didn't [28] 24/13 33/10 33/14 46/25 53/4 61/25 64/5 78/6 92/14 93/13 97/5 97/18 111/25 112/23 117/16 120/6 122/25 135/9 135/10 137/8 137/10 137/11 140/16 147/14 152/4 155/19 155/20 159/19</p> <p>Dietrich [2] 57/23 58/5</p> <p>differ [2] 117/22 129/23</p> <p>difference [12] 27/1 27/8 41/23 83/15 93/20 101/14 104/4 121/10 138/11 157/22</p>	<p>159/19 159/22</p> <p>differences [2] 35/14 115/21</p> <p>different [50] 12/25 15/4 16/8 16/8 16/9 16/14 17/3 25/17 31/7 35/4 35/6 39/12 39/17 47/12 48/2 51/2 51/12 51/13 53/15 59/2 79/15 82/24 92/10 92/21 93/1 95/20 102/8 102/13 104/25 112/14 114/15 115/13 115/14 115/21 118/3 119/13 119/14 120/19 120/20 127/11 132/14 138/4 140/24 142/17 149/20 153/18 154/5 156/25 157/2 160/12</p> <p>different Ranitidine [1] 119/13</p> <p>differently [4] 85/16 93/19 126/16 128/16</p> <p>difficult [3] 56/14 150/14 156/9</p> <p>dig [1] 125/19</p> <p>direct [3] 113/9 116/21 156/21</p> <p>directed [3] 5/10 6/8 46/3</p> <p>direction [1] 108/14</p> <p>directly [8] 73/6 103/22 122/21 135/5 144/16 144/19 150/10 153/7</p> <p>disagree [2] 158/5 158/7</p> <p>disagrees [1] 59/20</p> <p>discover [2] 58/1 136/16</p> <p>discovered [2] 19/2 47/6</p> <p>discovery [8] 50/23 51/16 114/18 115/16 117/11 118/17 119/23 123/15</p> <p>discrimination [1] 75/5</p> <p>discussed [9] 52/1 69/20 69/25 72/8 72/17 80/8 89/19 105/1 154/2</p> <p>discusses [1] 55/24</p> <p>discussing [2] 86/23 106/3</p> <p>discussion [13] 23/17 84/20 86/4 87/4 92/12 92/17 97/16 102/22 109/11 110/10 118/20 120/12 124/19</p> <p>discussions [2] 80/19 138/9</p> <p>dismiss [39] 1/9 3/2 7/3 8/17 12/17 13/17 38/25 39/4 42/21 62/12 63/16 63/21 66/12 66/22 80/15 81/2 97/14 120/22 121/1 121/24 123/25 124/8 124/9 124/24 126/13 128/24 129/9 134/2 137/17 137/18 137/23 138/2 138/3 138/24 144/12 155/4 155/19 155/20 161/18</p> <p>dismiss our [1] 138/24</p> <p>dismissal [5] 20/23 21/19 68/16 138/17 154/16</p> <p>dismissals [1] 10/19</p> <p>dismissed [12] 10/16 12/22 21/3 21/6 21/11 22/11 22/20 62/13 68/25 71/23 118/8 144/21</p> <p>disparate [1] 51/11</p> <p>dispensation [4] 75/5 76/18 77/4 111/19</p> <p>dispensed [2] 100/12 101/17</p>	<p>dispensing [1] 102/2</p> <p>dispersion [4] 51/3 78/2 114/19 119/12</p> <p>dispose [1] 63/5</p> <p>disposes [1] 31/2</p> <p>disposition [1] 98/25</p> <p>dispute [3] 5/12 72/5 85/12</p> <p>disputes [2] 27/20 32/10</p> <p>disputing [1] 6/2</p> <p>dissimilar [1] 16/12</p> <p>distinct [2] 12/24 16/16</p> <p>distinction [3] 56/11 83/18 95/2</p> <p>distinguish [2] 82/10 82/23</p> <p>distinguishable [2] 22/1 51/25</p> <p>distort [1] 16/11</p> <p>distribute [3] 68/11 72/9 90/23</p> <p>distribute suspect [1] 90/23</p> <p>distributing [1] 68/13</p> <p>distribution [8] 74/17 87/25 88/9 99/15 99/17 99/22 100/8 103/6</p> <p>distributor [18] 22/25 66/11 67/5 68/21 81/4 85/8 100/11 100/11 106/10 108/3 108/7 108/9 111/2 111/24 115/25 117/8 119/17 124/12</p> <p>distributors [83] 51/11 66/22 67/15 68/1 68/2 68/6 68/9 68/12 68/19 68/24 69/1 69/6 69/7 69/11 70/15 70/18 70/23 71/1 71/23 72/2 72/6 72/8 73/9 73/15 74/3 74/9 74/19 74/21 75/8 75/21 76/23 77/19 78/5 78/15 78/20 79/7 79/13 79/22 81/8 82/15 83/7 84/2 84/13 86/7 87/7 87/16 88/3 88/19 88/24 89/7 89/11 89/16 89/23 89/24 90/20 92/4 92/25 93/8 94/2 95/8 95/15 95/23 96/24 97/3 97/8 98/6 100/6 101/22 106/23 107/9 107/15 108/14 109/3 109/12 111/7 112/23 116/2 116/10 117/13 117/16 122/17 123/23 124/6</p> <p>distributors' [3] 68/14 104/13 124/7</p> <p>DISTRICT [11] 1/1 1/1 1/10 10/15 14/14 14/16 17/21 18/22 50/3 85/24 109/21</p> <p>diversity [1] 140/25</p> <p>divide [5] 7/11 8/1 81/20 125/4 125/11</p> <p>Dividing [1] 125/15</p> <p>DIVISION [1] 1/2</p> <p>DLA [1] 2/9</p> <p>do [107] 5/9 8/6 8/12 9/4 10/24 12/23 15/23 19/1 19/12 28/4 28/15 31/11 31/13 31/13 31/14 31/20 34/15 36/21 37/2 37/25 38/5 38/7 41/25 43/18 43/19 44/11 45/1 46/9 46/11 46/13 53/21 54/15 54/23 55/22 56/16 58/13 59/25 62/6 63/1 64/5 65/9 66/1 66/9</p>
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-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>D</p> <p>do... [64] 66/24 66/25 68/2 68/3 68/4 68/4 68/6 68/7 68/8 68/9 68/11 68/15 70/17 70/17 70/18 71/20 72/5 72/8 73/4 77/10 83/3 84/12 85/12 85/21 86/22 87/20 88/7 91/5 91/15 94/5 94/11 97/6 101/16 102/15 104/3 106/15 106/16 107/15 108/3 109/2 110/22 118/17 118/22 118/25 120/5 122/8 124/10 130/7 131/23 132/23 132/24 132/25 145/21 145/22 146/1 147/20 148/6 152/17 153/1 154/6 155/22 156/24 158/16 159/9</p> <p>docket [3] 7/2 66/23 88/6</p> <p>doctrine [2] 143/6 160/9</p> <p>documented [2] 123/12 123/13</p> <p>documents [1] 119/25</p> <p>does [37] 5/11 9/2 11/19 14/12 15/15 18/7 22/3 33/8 35/12 37/24 50/7 56/2 56/10 64/22 71/9 71/11 72/17 76/1 78/3 91/22 101/14 103/22 105/13 108/8 109/17 110/19 111/15 117/1 121/9 122/9 129/7 139/11 148/22 150/22 154/6 160/23 161/18</p> <p>doesn't [45] 4/14 6/11 6/12 13/8 22/1 22/2 33/20 33/24 34/8 36/17 36/23 37/4 47/16 48/3 48/8 53/7 59/20 75/12 76/9 76/24 76/25 77/1 93/18 93/20 94/5 100/20 101/20 109/6 119/21 120/23 121/16 122/12 132/11 137/3 141/5 141/24 142/11 142/15 143/12 144/9 148/3 153/3 153/23 154/14 155/11</p> <p>doing [10] 36/24 38/1 38/7 81/3 98/7 102/23 106/17 126/19 128/20 145/23</p> <p>dollar [2] 75/18 76/15</p> <p>dollars [1] 23/23</p> <p>don't [87] 3/20 19/13 19/18 26/9 34/5 38/12 39/24 45/9 45/11 45/12 45/14 45/17 50/21 51/5 51/8 51/14 51/15 56/25 59/15 59/24 60/19 60/25 61/20 62/3 63/15 63/17 67/3 68/5 73/25 77/9 77/17 77/19 77/22 78/16 80/8 82/4 85/19 85/24 86/11 93/10 94/8 102/15 103/4 103/15 107/15 107/20 112/21 113/14 113/23 113/25 114/3 114/18 115/14 115/15 116/4 116/21 118/15 118/16 118/17 118/23 119/20 120/5 121/21 122/23 123/7 125/18 135/25 138/2 138/24 139/9 140/11 143/12 148/4 152/5 152/20 154/13 154/21 155/4 155/8 155/10 156/1 158/19 158/20 159/21 159/24 160/1 160/8</p> <p>done [13] 36/16 51/1 53/10</p>	<p>54/22 55/8 56/25 65/15 83/3 84/10 94/12 97/21 98/2 150/3</p> <p>doors [1] 152/7</p> <p>dosage [1] 151/20</p> <p>dose [2] 11/16 28/8</p> <p>doubt [1] 96/12</p> <p>down [12] 24/1 24/14 47/6 74/17 84/2 99/3 119/4 130/6 132/16 150/13 160/14 160/15</p> <p>downstream [7] 71/1 83/2 85/5 85/20 96/23 101/16 101/20</p> <p>dozens [5] 16/20 16/21 16/21 53/24 83/6</p> <p>Drager [4] 18/20 54/24 57/19 57/20</p> <p>drawn [2] 45/18 114/17</p> <p>drop [2] 11/16 19/10</p> <p>dropped [1] 100/12</p> <p>drops [2] 44/3 44/5</p> <p>drug [103] 10/4 10/5 10/16 12/3 13/17 14/5 16/3 17/2 17/25 18/5 19/3 20/11 21/25 22/13 23/22 23/24 24/4 24/10 25/3 28/5 28/5 28/14 28/16 28/20 28/22 29/1 29/7 35/6 35/13 39/11 39/15 39/24 40/14 41/7 41/8 41/13 41/14 42/4 43/25 46/17 47/3 47/5 47/24 47/24 49/18 49/22 49/23 52/3 53/14 53/15 54/21 57/11 61/11 61/11 61/16 61/16 62/3 67/6 69/9 69/14 69/22 70/10 70/12 70/13 70/16 70/18 70/21 74/12 75/8 75/24 79/15 83/8 86/6 86/24 87/3 87/7 87/10 87/14 88/8 89/3 89/8 89/17 90/9 90/24 98/15 102/25 103/21 108/20 110/9 110/13 110/23 111/19 112/14 113/18 117/4 122/6 122/7 122/23 127/6 130/8 135/5 135/18 151/19</p> <p>Drug and [1] 127/6</p> <p>drug when [1] 29/1</p> <p>drug's [1] 11/2</p> <p>drugs [30] 8/23 21/16 21/21 22/2 23/21 29/3 32/18 40/5 40/6 72/9 72/14 76/24 77/1 77/3 85/10 85/13 87/13 88/5 90/23 92/15 92/15 107/25 109/13 110/14 110/16 110/17 110/20 110/21 113/7 122/11</p> <p>drugs and [1] 77/1</p> <p>drugs any [1] 85/10</p> <p>DSCSA [1] 81/9</p> <p>due [4] 29/18 33/10 108/24 141/4</p> <p>duplicates [1] 27/15</p> <p>duration [1] 151/20</p> <p>during [8] 3/24 9/24 51/9 77/20 77/24 82/22 91/20 92/17</p> <p>duties [88] 9/10 24/22 26/5 26/9 26/21 26/23 27/4 27/10 27/20 27/21 28/10 30/11 30/12 31/6 31/8 31/9 31/18 32/3 32/12 32/19 33/23 34/5</p>	<p>34/5 34/17 34/23 37/1 38/21 41/21 41/24 42/2 47/2 48/2 48/3 48/7 48/9 55/21 56/11 56/21 57/1 58/11 58/20 58/25 59/2 59/7 59/18 61/25 62/6 71/12 74/16 74/17 74/18 74/24 75/3 75/7 76/5 78/8 90/19 91/18 92/6 92/8 93/4 95/5 95/19 95/23 97/18 100/17 101/25 104/20 104/24 105/6 111/16 135/6 136/18 139/24 142/5 142/21 142/22 147/10 147/24 148/7 148/11 148/12 148/19 148/19 149/20 154/20 155/6 155/8</p> <p>duties created [1] 148/11</p> <p>duties to [1] 142/22</p> <p>duty [88] 9/12 9/14 9/19 9/23 10/5 10/10 10/10 14/4 14/5 18/24 20/2 20/4 21/16 27/5 27/7 27/7 27/7 27/24 28/15 32/7 32/7 32/11 32/16 33/9 33/13 33/15 34/24 35/3 35/10 35/10 35/24 37/25 38/6 39/19 41/1 43/4 51/21 52/14 52/21 53/21 54/12 54/12 54/13 56/3 56/4 56/17 58/12 59/9 59/11 59/14 60/7 60/13 61/1 61/22 61/24 70/4 71/10 96/13 98/5 98/10 101/25 102/6 102/7 102/17 102/17 102/18 102/19 102/19 102/23 106/16 108/4 111/18 122/1 123/10 123/11 128/18 130/7 139/13 139/23 140/5 145/22 148/17 148/20 148/21 148/22 149/1 149/7 150/20</p> <p>duty as [1] 140/5</p> <hr/> <p>E</p> <p>e's [1] 127/21</p> <p>each [13] 3/18 44/6 44/10 44/17 62/7 106/5 135/25 136/3 136/15 138/7 139/25 140/9 151/12</p> <p>earlier [12] 73/11 79/8 102/5 106/1 106/13 114/13 116/6 116/16 131/24 135/4 142/17 148/18</p> <p>early [1] 132/4</p> <p>ease [1] 82/9</p> <p>easier [3] 80/10 123/16 148/24</p> <p>easiest [1] 149/11</p> <p>easily [1] 118/2</p> <p>East [1] 1/23</p> <p>Eastern [1] 109/21</p> <p>easy [2] 4/5 56/15</p> <p>economic [13] 69/10 127/5 127/10 153/14 153/17 153/24 154/4 154/7 158/11 160/9 160/10 160/13 160/14</p> <p>effect [14] 10/22 42/12 84/16 86/25 99/14 103/18 104/12 104/13 104/15 104/17 104/18 105/8 105/9 105/10</p> <p>effective [1] 42/19</p> <p>efficacy [3] 32/18 77/3</p>
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>E</p> <p>efficacy... [1] 132/20</p> <p>efficiency [1] 82/9</p> <p>efficient [1] 32/9</p> <p>effort [3] 16/23 57/17 58/6</p> <p>efforts [2] 16/19 42/20</p> <p>efforts to [1] 16/19</p> <p>eight [2] 81/16 81/24</p> <p>EISENSTEIN [10] 2/8 17/5 69/13 125/7 126/1 126/1 129/4 143/22 152/20 152/23</p> <p>Eisenstein's [1] 126/4</p> <p>either [12] 19/2 27/6 53/18 70/17 91/17 96/20 114/1 127/4 132/3 144/1 154/15 161/2</p> <p>Electric [4] 96/3 96/5 96/14 96/18</p> <p>electricity [1] 96/8</p> <p>elements [4] 27/10 27/11 27/13 118/24</p> <p>elephant [1] 29/8</p> <p>elevated [1] 117/3</p> <p>Eleventh [8] 11/6 26/22 48/15 52/16 52/17 53/6 57/19 98/21</p> <p>eliminates [1] 69/6</p> <p>else [4] 46/13 50/18 112/18 144/11</p> <p>email [4] 3/7 3/9 3/21 4/7</p> <p>embodied [1] 25/8</p> <p>embrace [2] 33/13 97/23</p> <p>embraced [5] 24/18 56/3 138/16 151/22 151/25</p> <p>embraced our [1] 24/18</p> <p>embraces [2] 32/10 33/15</p> <p>emerging [4] 32/17 34/3 139/17 139/22</p> <p>Emory [2] 116/17 117/3</p> <p>employee [1] 109/18</p> <p>employer [2] 109/18 109/19</p> <p>en [1] 32/22</p> <p>enact [1] 97/24</p> <p>enactment [2] 103/24 105/14</p> <p>encompasses [2] 34/24 59/8</p> <p>end [15] 13/13 16/7 29/10 29/25 41/18 47/13 49/5 49/16 52/6 66/25 71/6 86/3 105/17 133/17 134/3</p> <p>endeavor [1] 161/8</p> <p>ends [1] 84/20</p> <p>enforce [3] 33/22 34/6 99/1</p> <p>enforcing [1] 76/13</p> <p>engage [1] 78/6</p> <p>engaged [1] 101/18</p> <p>English [2] 136/17 136/19</p> <p>enough [4] 26/19 45/10 119/23 149/20</p> <p>enough in [1] 26/19</p> <p>ensure [6] 3/16 40/13 44/9 77/2 78/16 120/17</p> <p>ensuring [1] 104/4</p> <p>entered [1] 23/25</p> <p>entertained [1] 86/18</p> <p>entire [7] 18/16 67/3 74/1 83/6 99/3 99/21 103/3</p> <p>entirely [4] 22/6 49/23</p>	<p>87/22 136/15</p> <p>entirety [4] 38/19 88/10 152/16 152/25</p> <p>entities [4] 5/24 85/5 115/10 141/21</p> <p>entitled [4] 33/12 45/24 56/22 109/19</p> <p>entity [2] 113/11 115/9</p> <p>Entry [2] 7/2 66/23</p> <p>equal [1] 92/4</p> <p>equivalence [1] 9/17</p> <p>equivalent [1] 131/13</p> <p>Erie [5] 33/11 33/12 56/1 97/22 159/4</p> <p>Erie guess [1] 33/11</p> <p>erroneous [1] 33/12</p> <p>error [1] 30/16</p> <p>escape [2] 11/9 21/24</p> <p>escaped [1] 13/4</p> <p>especially [4] 82/17 115/20 116/10 133/21</p> <p>ESQ [11] 1/11 1/16 1/19 1/22 2/1 2/4 2/4 2/8 2/8 2/12 2/12</p> <p>essentially [2] 9/15 67/7</p> <p>establish [7] 48/24 56/23 63/11 99/13 114/2 137/3 149/8</p> <p>established [5] 8/21 48/18 49/9 70/2 132/2</p> <p>establishes [2] 49/13 137/2</p> <p>evaluate [3] 126/23 131/3 131/11</p> <p>even [55] 17/1 19/16 24/3 25/6 29/1 36/16 40/20 41/3 53/11 56/3 56/16 56/20 63/15 64/15 64/20 65/22 68/22 70/15 71/19 75/12 83/23 84/15 86/21 91/15 96/24 96/25 98/1 100/19 108/1 108/22 109/19 116/22 116/24 117/21 118/25 119/18 121/12 127/25 132/3 132/12 134/15 135/18 137/22 138/5 138/24 140/11 140/23 145/2 145/2 148/19 149/23 151/18 151/19 154/22 160/17</p> <p>evening [1] 161/20</p> <p>ever [4] 23/24 39/12 39/16 98/18</p> <p>every [24] 11/15 11/16 11/16 11/16 11/16 12/21 19/10 19/11 19/11 19/20 29/9 30/8 56/2 57/17 58/7 78/8 96/11 97/22 126/20 138/16 140/14 141/9 142/18 156/20</p> <p>every pill [1] 19/20</p> <p>everybody [5] 4/6 37/10 80/13 83/13 95/20</p> <p>everyone [4] 3/1 44/11 161/1 161/19</p> <p>everything [4] 36/22 93/11 119/25 119/25</p> <p>everywhere [3] 24/11 27/25 149/19</p> <p>evidence [6] 24/25 30/4 110/3 124/3 132/11 132/12</p> <p>evinces [1] 104/15</p>	<p>exact [12] 29/3 29/11 31/12 32/13 34/5 35/1 35/22 36/6 59/12 92/20 96/4 140/5</p> <p>exactly [8] 28/15 30/11 31/9 49/22 89/21 123/13 150/9 150/16</p> <p>examine [1] 8/25</p> <p>example [27] 11/5 27/3 31/17 33/14 40/4 40/6 46/6 46/20 47/4 58/15 58/18 60/15 60/22 64/25 95/25 101/9 110/15 112/10 112/19 113/2 115/8 119/3 119/3 136/3 142/4 155/11 158/19</p> <p>example of [1] 142/4</p> <p>example to [1] 60/15</p> <p>examples [4] 45/5 60/8 90/16 113/19</p> <p>exceeded [1] 77/22</p> <p>except [1] 106/23</p> <p>exception [16] 35/14 35/24 74/23 75/4 75/13 75/20 76/1 76/8 77/5 79/3 79/18 101/12 111/22 150/8 150/10 150/17</p> <p>exceptions [3] 19/23 83/13 97/15</p> <p>excised [1] 126/22</p> <p>exclude [1] 72/13</p> <p>exclusively [2] 122/24 123/1</p> <p>excursions [4] 49/11 117/24 118/3 119/18</p> <p>excuse [2] 22/10 73/1</p> <p>exemption [1] 12/12</p> <p>exercise [1] 159/23</p> <p>exerting [1] 152/17</p> <p>exist [5] 9/1 13/8 92/14 142/25 143/25</p> <p>existed [2] 95/18 104/16</p> <p>exists [3] 53/22 71/18 113/10</p> <p>expand [3] 54/2 54/10 84/23</p> <p>expanded [1] 55/5</p> <p>expansion [1] 86/1</p> <p>expect [2] 4/6 8/6</p> <p>expected [2] 23/25 89/23</p> <p>expects [1] 85/10</p> <p>expeditions [1] 161/9</p> <p>experts [1] 62/4</p> <p>expiration [54] 19/9 19/13 19/14 19/17 19/23 23/15 34/20 34/25 35/4 35/5 35/14 35/15 35/25 36/5 36/9 36/14 36/19 36/25 39/12 39/17 39/19 39/22 39/24 40/5 40/7 40/11 40/12 40/20 41/2 41/10 41/20 42/9 42/17 42/19 42/20 43/7 43/10 44/8 44/19 45/2 45/4 45/7 45/23 58/15 59/14 59/16 64/2 79/11 92/1 92/2 92/23 93/7 93/13 139/6</p> <p>explain [2] 52/20 146/11</p> <p>explained [8] 21/2 46/9 52/17 53/25 83/10 87/11 101/24 101/25</p> <p>explaining [1] 105/2</p> <p>explains [1] 88/13</p> <p>explanation [1] 51/12</p> <p>explicit [1] 90/8</p>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

E explicitly [3] 14/10 150/12 150/21 exploded [1] 96/8 explore [1] 82/20 exposed [1] 44/9 exposing [1] 119/8 exposure [3] 43/10 78/14 122/15 exposures [1] 122/16 express [69] 14/18 14/22 14/22 15/2 15/11 15/12 16/2 16/5 16/17 17/1 17/6 17/9 17/13 22/5 25/18 30/18 30/22 31/3 31/23 35/13 39/22 49/20 49/24 50/6 57/13 63/10 64/1 64/6 64/17 64/21 65/17 65/23 69/8 72/19 87/18 90/13 99/6 99/11 100/17 105/4 122/25 123/2 127/2 128/2 129/11 129/16 129/19 133/7 134/12 138/20 139/12 139/12 140/7 140/13 142/10 142/14 142/18 142/20 142/23 142/25 143/12 155/19 156/17 156/22 157/4 157/18 157/23 158/1 158/4 express preemption [2] 30/18 133/7 expressed [3] 14/23 34/22 104/2 expressly [15] 15/8 34/11 35/16 69/9 69/14 88/8 105/16 110/23 123/4 127/7 127/15 140/13 155/24 156/19 156/19 extend [1] 83/5 extension [1] 22/12 extensive [1] 77/21 extensively [1] 74/8 extent [25] 26/25 27/8 40/10 40/23 41/23 46/16 48/23 61/22 68/20 72/21 79/20 117/20 118/6 118/9 121/9 121/18 129/22 138/11 139/15 140/12 144/13 144/16 144/22 149/8 154/19 extremely [3] 115/4 116/15 142/20 eye [3] 44/3 44/5 82/21	143/16 149/8 factual [6] 11/23 77/18 114/11 116/25 118/5 118/25 Fahrenheit [2] 47/5 112/7 fail [6] 22/20 69/18 72/6 73/9 82/23 84/6 failed [4] 13/15 43/9 46/7 48/24 fails [5] 16/25 21/10 21/24 54/18 128/5 failure [46] 14/7 14/10 14/15 19/8 23/15 31/25 34/13 34/24 37/19 51/21 52/3 52/13 52/21 53/13 55/1 57/25 57/25 58/1 58/16 59/4 59/5 59/7 59/13 59/16 59/17 60/6 60/12 60/20 60/21 60/23 60/23 61/2 61/3 61/4 63/22 70/9 85/8 127/18 128/23 133/3 134/10 138/24 139/13 155/4 156/3 156/15 failures [1] 72/12 fair [7] 10/20 10/21 13/21 50/19 81/13 81/17 82/12 fairly [3] 83/16 113/16 160/7 faith [17] 74/23 75/4 75/13 75/20 75/24 76/1 76/8 76/18 76/25 77/4 77/5 101/12 111/18 111/22 117/11 118/11 147/15 faithful [1] 9/19 fall [7] 11/2 12/9 105/3 126/18 132/24 154/12 155/11 fallacy [1] 33/2 falls [4] 88/17 106/24 156/22 157/3 false [5] 28/6 28/24 44/12 44/15 49/7 familiar [2] 8/19 97/9 family [1] 6/1 far [2] 14/20 95/11 fares [1] 17/4 farther [1] 131/6 fashioned [1] 53/12 fatal [1] 113/23 fault [3] 96/25 97/5 98/4 faulted [1] 94/18 faulty [1] 120/6 favor [5] 11/12 16/22 45/19 45/24 114/18 FDA [121] 14/4 14/11 14/15 20/12 21/20 22/1 22/3 22/13 23/15 23/20 24/12 24/13 24/17 24/24 25/2 25/4 28/20 28/21 29/1 29/4 30/3 30/4 30/7 31/25 32/8 32/12 33/9 34/2 34/13 36/3 38/23 39/3 39/16 39/20 39/21 40/11 40/12 42/8 43/25 47/1 48/25 51/1 51/13 51/21 52/4 52/11 52/14 52/14 52/21 52/24 53/5 53/13 54/13 55/1 55/4 55/7 55/8 55/10 56/15 56/25 57/3 58/2 58/17 60/6 60/20 61/13 61/21 62/4 64/22 64/25 72/19 77/12 78/2 78/13 78/21 79/14 79/16 84/14 92/15 101/18	101/19 108/8 108/21 108/22 109/1 112/8 112/10 113/7 113/11 114/15 115/4 115/10 116/14 116/17 118/18 119/12 126/12 127/13 128/7 128/9 128/19 132/1 132/2 132/6 132/7 133/4 134/17 135/11 135/18 136/12 137/8 139/19 144/20 151/14 151/18 152/9 156/18 156/21 157/2 157/16 157/19 FDA approved [1] 128/7 FDA insisting [1] 39/21 FDA tomorrow [1] 34/2 FDA's [13] 32/13 34/10 36/9 39/18 42/5 51/4 52/5 91/15 108/14 115/18 137/1 139/9 157/11 FDCA [10] 28/4 29/5 34/1 49/1 70/4 74/13 74/23 75/2 139/20 153/19 FDCA's [1] 127/12 feature [1] 12/11 February [1] 22/23 federal [189] Federal Insecticide [1] 90/14 Federal requirements [1] 131/12 Federally [3] 112/24 130/13 132/21 feel [1] 150/6 festive [1] 4/19 few [9] 3/22 17/12 30/15 82/17 90/16 103/11 129/10 140/16 159/13 fewer [1] 131/6 field [7] 15/5 25/20 37/7 134/4 143/5 143/8 143/13 Fifth [3] 18/21 50/2 54/25 fight [2] 112/21 154/22 file [2] 117/10 121/23 filed [2] 3/3 106/2 files [1] 17/7 filing [1] 127/10 fill [1] 68/7 final [7] 77/7 80/2 90/5 98/14 105/13 105/14 142/1 finally [5] 27/9 34/7 49/17 69/17 102/25 find [7] 11/11 13/13 13/13 13/23 13/24 140/11 140/16 finding [6] 27/14 37/4 39/23 132/5 132/14 137/12 findings [1] 132/7 fine [4] 75/18 76/15 94/15 122/3 finer [1] 70/7 fingertips [1] 39/25 first [48] 3/5 7/1 8/25 11/13 12/7 13/22 14/4 16/23 17/18 23/19 23/24 26/9 28/4 28/19 29/24 32/24 44/1 62/9 63/7 66/5 69/4 78/8 82/22 84/3 86/13 87/18 87/22 92/18 98/20 98/22 101/3 103/2 103/15 104/23 107/2 109/22 113/15 114/6 116/4 116/21
F F.App'x [1] 52/17 F.Supp [1] 109/20 F.Supp.3d [1] 22/23 face [1] 56/14 faced [1] 13/16 facilities [4] 46/13 50/22 51/9 51/16 facility [1] 50/16 fact [22] 4/4 13/15 23/22 24/21 35/7 37/2 55/5 73/5 83/14 89/15 93/13 93/15 104/20 109/7 114/10 117/5 119/1 119/11 123/12 134/8 150/9 150/21 facto [1] 135/12 factory [1] 122/17 facts [4] 92/20 115/17		

F first... [8] 122/21 133/9 142/18 145/1 154/18 155/22 160/17 161/17 Fisher [1] 5/2 fit [1] 123/4 five [6] 2/9 8/9 49/10 67/4 81/14 81/18 fix [1] 85/10 FL [2] 1/5 2/18 flaw [1] 12/4 flds.uscourts.gov [1] 4/9 flexibility [1] 93/21 flip [2] 26/1 45/17 flipped [1] 96/8 floor [2] 1/20 157/15 FLORIDA [7] 1/1 14/14 14/16 18/22 50/4 77/24 85/24 flouting [2] 48/9 78/20 flow [3] 160/11 160/14 160/15 flowed [1] 96/8 flows [1] 25/13 flsd.uscourts.gov [1] 3/10 focus [6] 17/11 50/5 96/1 102/18 149/6 149/11 focused [4] 54/19 65/12 131/20 149/25 focuses [1] 87/22 follow [8] 9/16 9/23 20/5 56/1 81/6 100/2 100/5 107/2 followed [2] 32/22 100/9 following [8] 3/6 4/22 9/20 51/22 61/14 96/1 109/10 136/23 follows [1] 26/1 followup [7] 6/14 41/12 50/14 58/8 64/10 118/12 158/9 fond [1] 144/14 Fontem [4] 104/13 105/9 105/12 105/14 Food [5] 14/5 69/9 69/22 127/6 135/5 footnote [14] 28/25 29/14 29/16 74/14 116/16 135/16 143/23 151/1 151/13 151/17 152/16 152/25 153/10 155/1 Footnote 4 [1] 29/16 footprints [2] 100/2 100/9 for implied [1] 151/3 forbidden [1] 88/24 force [2] 42/12 92/4 foreclose [1] 64/22 foreclosed [2] 34/8 93/23 forecloses [4] 64/16 64/20 102/2 102/24 forecloses Magnuson-Moss [1] 64/16 foregoing [1] 162/1 foreign [1] 15/14 foremost [1] 63/8 foreordained [1] 11/19 forgets [1] 36/21 forgot [1] 61/8 form [7] 32/10 33/13 73/4 78/3 112/25 131/16 158/15	formal [1] 109/2 formation [2] 83/23 84/5 formed [6] 45/12 45/13 45/14 85/17 115/19 119/10 former [1] 46/14 forming [2] 114/16 137/10 forms [4] 45/10 51/3 51/4 113/17 formulaic [1] 18/16 formulation [16] 10/5 12/13 27/23 36/23 42/7 70/12 70/20 84/14 126/12 127/13 128/7 128/10 128/25 130/15 132/22 149/10 formulations [2] 20/5 72/10 forth [8] 8/20 9/11 47/1 48/12 82/15 142/2 142/16 161/12 forthcoming [2] 91/3 101/8 forward [4] 21/1 137/25 149/24 161/14 found [20] 9/8 12/22 13/11 16/21 39/16 44/4 51/13 58/4 96/3 105/2 105/10 113/5 113/8 114/6 128/6 140/16 140/23 140/24 156/21 160/6 four [4] 8/9 14/2 69/3 81/16 four high-level [1] 69/3 Fourth [3] 18/20 54/24 57/20 frame [5] 92/10 92/12 107/16 107/21 107/21 framework [1] 12/9 franchise [1] 23/22 Frankfurter [1] 75/11 free [3] 135/23 144/9 152/14 free-standing [1] 144/9 freely [2] 94/3 94/4 frequency [2] 28/8 151/20 Friday [1] 161/16 friend [16] 29/12 30/15 44/21 77/9 95/9 98/15 99/4 99/10 100/18 102/22 103/10 136/20 137/21 151/12 157/7 158/5 friends [4] 31/10 75/20 91/12 135/3 from complying [1] 48/4 from manufacturers [1] 89/24 front [5] 24/12 66/25 141/19 153/10 155/2 Ft [1] 2/18 fueled [1] 37/4 fulfill [1] 148/22 full [6] 42/12 49/14 93/21 99/9 114/18 115/16 fully [4] 41/19 61/21 63/3 71/25 function [1] 98/24 functional [2] 10/24 19/5 fundamental [5] 12/11 17/23 18/23 84/23 103/12 Fungicide [2] 90/14 105/5 further [1] 25/7 future [1] 104/6	garden [1] 11/7 gave [3] 95/9 96/5 113/2 gaze [1] 13/4 general [8] 5/4 76/13 83/16 96/3 96/5 96/14 96/18 122/10 generalized [1] 130/25 generally [1] 160/4 generic [55] 7/3 7/14 8/17 8/23 8/23 9/1 9/3 9/6 9/16 10/4 10/16 11/25 13/17 16/3 16/15 16/22 17/2 17/15 17/20 17/25 18/5 20/3 21/4 21/15 29/15 32/14 33/5 34/2 34/17 35/1 36/8 39/11 39/15 40/6 43/1 43/13 43/16 44/6 44/6 49/22 52/3 53/20 54/21 59/12 61/11 64/3 65/13 68/5 70/10 74/8 82/15 92/24 136/3 136/5 136/7 generic's [1] 9/23 generics [17] 9/10 12/5 12/18 17/7 17/12 18/15 19/24 21/20 22/2 23/25 43/4 69/23 79/6 79/18 84/1 92/1 101/7 generics' [1] 72/1 get [27] 4/3 4/12 29/23 45/17 49/15 50/23 57/3 61/23 64/6 78/16 79/19 86/8 92/11 107/3 119/22 119/23 120/1 123/14 131/23 135/22 138/17 149/6 154/17 154/22 155/8 156/11 158/22 gets [3] 13/3 99/7 113/21 getting [2] 32/9 119/24 give [8] 10/22 60/15 64/18 81/17 90/15 130/16 135/22 159/3 given [8] 3/21 11/24 12/16 51/7 86/1 86/19 115/13 140/19 gives [3] 15/17 47/20 100/4 giving [1] 7/12 glean [2] 115/17 148/17 go [23] 9/14 11/13 12/10 12/20 12/21 21/4 27/9 40/19 55/4 64/17 66/17 75/17 78/23 85/11 108/23 123/6 133/8 137/11 141/13 144/25 149/24 155/1 158/8 goal [1] 82/16 goes [5] 8/24 11/7 77/7 99/18 152/19 going [27] 4/11 4/12 6/19 7/1 7/23 8/4 17/11 20/10 53/23 55/10 56/24 57/6 59/1 60/12 67/8 67/14 69/12 74/5 87/2 92/16 94/20 105/22 107/5 121/22 137/15 137/19 149/19 Goldenberg [1] 97/10 good [46] 3/1 4/16 4/17 4/18 7/13 8/16 11/5 23/7 23/11 31/24 33/18 48/18 58/24 66/16 74/22 75/4 75/13 75/20 75/24 76/1 76/7 76/18 76/25 77/1 77/2 77/4 77/5 80/22 82/7 91/8 94/17 96/18 101/12 111/18 111/22 114/7 115/20
	G game [2] 33/6 57/2 game of [1] 33/6	

G good... [9] 117/11 118/10 125/6 125/21 125/23 134/22 147/15 148/23 156/23 Goodell [1] 2/13 got [2] 8/14 154/1 governed [5] 21/15 21/16 62/15 64/14 69/21 Government [3] 76/22 77/2 153/2 governs [1] 36/3 grabs [1] 133/5 granted [2] 128/17 137/19 grappled [1] 135/17 grasp [1] 11/9 gravamen [1] 126/14 great [3] 41/17 47/10 125/19 greater [1] 119/9 ground [5] 66/12 82/16 91/11 135/9 135/10 grounds [7] 7/4 10/17 39/1 66/22 80/15 124/8 124/10 group [5] 82/19 83/22 85/16 116/22 124/8 group-specific [1] 124/8 groups [3] 22/25 81/10 82/9 guarantees [1] 28/22 guard [1] 53/7 Guarino [5] 11/6 50/4 57/19 57/19 142/12 guess [4] 30/3 33/11 33/12 159/3 GUGERTY [7] 2/12 7/16 7/21 8/5 8/9 20/17 54/1 guidance [2] 36/4 38/24 guide [1] 92/12 guidelines [1] 49/9 Gustafson [1] 44/1 Guyer [2] 142/14 143/2	26/6 34/21 35/12 36/3 39/12 39/15 44/18 45/9 51/1 51/13 51/25 53/12 54/20 57/3 57/3 57/17 62/16 77/12 78/13 79/16 83/3 87/18 95/18 96/23 98/9 98/18 98/19 107/7 110/10 110/15 111/24 114/1 116/5 116/14 118/10 119/12 126/20 126/21 128/6 128/9 130/20 132/6 135/17 137/19 141/20 142/3 142/6 142/13 144/2 144/2 144/5 149/9 150/3 152/8 155/25 156/21 157/12 157/13 161/7 161/15 has the [1] 44/18 have [348] have to [1] 78/15 haven't [6] 97/21 98/4 118/17 141/15 143/6 149/16 having [4] 73/14 126/22 138/9 149/19 hazards [1] 60/7 he [16] 7/19 34/21 81/7 101/25 102/5 103/10 120/21 131/25 132/3 144/12 144/12 152/18 152/25 153/1 153/3 153/5 head [2] 132/19 150/13 head-on [1] 132/19 heads [1] 93/9 health [5] 28/8 29/2 57/25 66/20 151/19 hear [14] 4/2 7/1 15/23 23/8 23/9 66/11 67/15 67/17 107/6 125/22 125/23 125/24 150/14 156/8 heard [23] 25/18 29/11 30/15 36/12 42/14 68/18 73/10 77/9 80/3 82/22 84/1 84/7 105/23 124/22 129/5 131/24 134/10 136/10 142/9 142/12 147/14 152/4 160/24 hearing [4] 1/9 60/4 64/19 161/21 hearings [1] 3/2 heart [2] 128/14 130/3 heartland [1] 61/6 held [15] 10/2 15/6 16/1 21/19 22/21 44/2 46/20 49/2 54/14 70/22 70/25 71/14 127/17 132/10 155/25 help [5] 7/12 34/10 52/6 53/13 67/13 helpful [1] 161/7 helps [1] 67/19 her [11] 3/9 3/16 3/17 3/22 17/8 27/6 87/3 92/19 93/16 93/17 93/25 herbicides [1] 17/2 here [69] 3/1 4/1 11/13 11/14 12/19 15/1 15/22 18/23 19/13 20/9 25/20 30/6 30/10 31/6 49/7 49/8 50/23 52/1 53/11 56/24 57/17 58/25 62/17 63/15 66/21 67/20 69/21 76/7 76/11 79/21 83/2 83/11 83/22 84/9 84/16 86/14 86/18 87/16 89/10 90/8 90/18	94/1 95/17 102/17 104/11 109/11 113/16 114/18 118/15 124/4 126/24 129/8 129/24 130/19 137/15 138/21 140/14 141/1 141/19 142/19 143/9 143/17 145/9 154/8 156/23 157/23 158/3 159/21 160/17 here as [1] 129/8 Heritage [1] 100/3 hide [1] 33/6 high [6] 69/3 77/14 115/5 116/15 122/15 122/16 higher [3] 112/18 119/4 119/9 highly [2] 27/3 59/3 hinge [4] 100/7 100/16 130/24 155/7 his [10] 34/21 36/12 81/8 132/4 134/21 142/17 144/13 144/15 145/1 150/22 history [2] 99/18 99/18 hit [3] 75/1 77/7 153/3 hold [8] 15/21 22/13 68/4 68/5 70/11 70/17 70/17 72/9 holder [7] 6/10 35/22 39/21 44/18 70/13 79/14 108/25 holders [9] 6/8 22/16 35/18 35/19 36/3 84/15 84/16 91/13 91/13 holding [7] 10/9 29/19 29/20 83/6 96/22 153/3 153/8 holdings [4] 12/16 12/24 16/20 53/25 holds [1] 139/8 holidays [1] 4/18 Holland [1] 1/19 Holliday [1] 109/20 home [9] 5/15 96/3 96/4 96/5 96/6 96/12 96/13 96/16 96/21 homeopathic [2] 21/25 22/2 hometown [1] 77/23 HON [1] 2/17 honest [1] 63/21 honor [183] Honor's [10] 7/18 47/16 54/11 55/2 55/11 57/22 123/6 136/25 145/12 155/1 HONORABLE [1] 1/9 hook [4] 42/20 45/2 45/20 83/13 hope [7] 1/20 4/14 25/9 117/11 123/12 123/15 156/13 hopefully [1] 6/24 hoping [1] 152/24 HORTON [8] 2/8 69/13 125/10 125/12 125/25 129/3 129/11 134/7 hot [3] 77/20 77/24 123/7 hound [1] 100/5 hour [1] 66/9 how [31] 4/16 4/17 7/11 8/1 11/5 12/18 31/10 31/13 45/9 45/11 45/12 51/2 52/20 53/23 67/19 80/20 87/19 90/6 100/1 100/7 115/18 118/17 125/5 129/7 129/11 129/11 139/11 142/16 148/6 148/16 158/17 however [9] 41/20 52/9 59/20
H had [21] 4/22 19/9 24/17 39/12 39/24 45/6 57/1 64/4 64/19 64/25 70/13 77/2 81/16 89/4 111/12 113/7 138/14 139/23 140/3 160/24 161/2 hadn't [1] 92/15 Hampshire [4] 27/24 138/15 149/2 149/18 hand [2] 56/12 129/20 handle [3] 7/19 79/15 117/16 handling [5] 7/16 8/10 17/5 46/8 118/3 hapless [1] 97/1 happen [1] 133/17 happened [1] 24/1 happy [8] 4/18 20/16 37/6 59/22 59/25 87/4 105/18 148/23 harbor [1] 12/13 harm [4] 54/16 54/23 55/11 153/17 harmony [1] 26/10 harms [5] 127/10 145/6 160/10 160/14 160/14 has [69] 3/15 3/24 5/2 8/25 13/17 15/22 16/2 17/14 18/19		

H however... [6] 81/20 105/16 110/19 112/8 126/7 127/6 human [1] 45/13 hundred [1] 136/23 hurdle [2] 56/14 57/6 hypothetical [18] 47/16 54/12 55/2 55/12 55/21 59/3 62/2 71/17 93/19 96/1 96/10 112/16 112/21 114/4 143/24 151/1 153/2 153/6 hypothetically [2] 31/18 53/11	63/25 64/7 64/23 64/24 65/1 65/1 65/5 65/11 65/18 65/21 65/23 65/24 72/21 73/2 73/6 127/3 128/11 128/22 129/12 133/7 134/13 142/11 142/15 142/24 143/3 143/4 143/14 143/15 150/8 150/11 150/17 151/3 153/4 155/20 156/15 157/17 157/22 158/1 implied warranty [2] 63/25 73/2 impliedly [2] 10/6 128/17 implying [1] 158/6 import [2] 87/10 153/7 importance [1] 6/24 important [18] 6/23 6/23 29/12 30/14 43/6 43/14 82/20 83/1 86/1 97/7 97/15 99/10 104/23 135/24 137/16 138/8 141/1 147/11 Importantly [1] 143/5 impose [14] 34/4 39/18 40/4 48/6 55/21 58/11 59/2 59/6 61/22 76/14 110/24 130/7 132/17 144/9 imposed [8] 40/19 58/20 74/25 77/4 91/22 92/6 95/20 104/5 imposes [10] 27/20 37/25 38/6 87/19 95/15 96/13 106/16 111/17 145/4 145/22 imposing [2] 25/6 157/1 impossibility [28] 10/7 25/21 25/22 30/21 31/22 31/22 33/1 37/24 38/5 38/10 38/13 41/4 41/6 43/20 45/20 47/18 47/22 69/5 70/1 106/15 112/12 142/24 143/3 143/15 143/16 145/21 149/14 157/17 impossibility preemption [1] 106/15 impossibility to [1] 31/22 impossible [22] 25/24 26/3 27/5 31/11 31/14 31/20 32/20 33/3 38/20 40/16 42/1 47/19 93/3 93/22 94/11 112/19 128/17 134/16 142/6 143/16 148/21 150/18 impression [1] 13/3 improper [4] 114/10 115/5 116/14 118/14 in effect [1] 104/13 in Yasmin [1] 17/21 inaccurate [6] 36/20 45/4 45/7 45/23 59/14 139/18 inadequate [3] 18/9 77/13 84/6 inapplicable [4] 21/13 62/14 64/13 86/14 inapposite [1] 30/22 inappropriate [2] 62/19 62/22 inaudible [7] 3/23 114/20 123/21 152/19 155/21 155/23 156/3 Inc [4] 5/2 52/7 66/20 66/20 inception [1] 83/24 include [5] 67/19 89/14	110/19 131/6 148/13 included [1] 89/20 includes [6] 32/7 59/13 85/23 88/10 88/13 88/22 including [7] 22/21 29/3 49/2 83/17 99/16 103/6 147/4 inconsistency [1] 49/16 inconsistent [6] 40/23 44/12 47/13 49/6 90/10 90/17 inconsistently [1] 44/12 incorporate [2] 63/17 136/4 incorporated [5] 5/20 7/4 66/13 80/16 124/25 incorporation [1] 5/16 incorrect [5] 35/8 126/10 127/20 130/12 135/14 incorrectly [1] 86/9 incumbent [1] 139/18 indeed [4] 26/13 103/22 117/24 123/3 independent [2] 65/6 73/8 independently [8] 9/7 43/4 43/13 43/18 43/20 44/11 84/10 110/21 Indianapolis [1] 2/6 indiscriminately [1] 83/16 individual [1] 141/6 individually [1] 127/4 industry [2] 23/22 38/24 infect [1] 49/25 inference [4] 50/24 51/7 114/17 115/13 inferences [2] 45/18 45/24 inform [2] 83/14 84/6 information [16] 24/12 25/2 56/16 62/4 78/1 88/14 88/20 89/18 110/17 111/12 135/19 137/4 139/22 152/9 157/13 157/21 inherent [4] 11/25 12/4 42/23 56/18 inherently [5] 11/18 55/3 84/3 113/20 126/15 initial [1] 35/5 initially [2] 34/21 35/25 injunction [3] 76/23 111/23 112/1 injured [2] 102/20 109/18 injuries [2] 43/5 76/16 injury [22] 4/24 22/7 27/12 45/6 46/6 69/2 77/12 96/9 96/12 114/8 116/13 124/14 127/21 127/23 127/24 128/13 146/6 149/22 154/7 158/10 158/11 158/15 Innocence [1] 98/4 innocent [3] 97/12 97/17 97/25 innovator [4] 4/21 5/21 6/6 6/10 inquiry [6] 8/25 54/19 54/21 56/12 129/19 148/24 Insecticide [2] 90/14 105/5 insert [1] 15/19 inside [1] 47/22 insight [1] 95/17 insist [2] 89/13 89/16 insisting [2] 39/21 40/17
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

I insists [1] 40/12 insofar [1] 27/14 inspect [1] 19/8 Inspection [1] 90/15 instability [1] 84/4 instance [3] 41/6 57/17 62/9 instances [1] 58/4 instead [13] 57/12 86/4 86/8 108/23 116/6 128/22 130/21 131/21 141/2 142/9 152/16 152/25 159/5 instruct [2] 52/10 53/4 instructed [2] 49/24 57/3 instructions [3] 46/8 78/20 96/6 insulated [1] 68/14 insurance [1] 98/6 intellectually [1] 63/20 intended [1] 104/3 intent [1] 105/11 intention [3] 14/24 15/11 104/15 interest [1] 17/11 interesting [1] 102/5 internal [1] 128/5 International [1] 66/20 interpret [1] 159/10 interpretation [3] 98/21 100/23 116/24 interpretive [1] 36/4 interstate [5] 28/14 75/24 77/3 111/20 112/3 intervening [1] 10/14 introduce [6] 7/9 28/13 66/18 74/22 80/17 125/13 introduced [1] 74/9 introducing [1] 125/10 introduction [1] 126/4 intuition [1] 97/20 investigate [4] 88/4 88/20 89/16 90/20 investigation [4] 88/15 88/17 89/22 110/25 invitation [1] 30/1 invite [2] 37/9 80/4 inviting [1] 29/21 invoke [1] 57/17 involve [3] 57/23 122/12 122/18 involved [2] 50/6 131/5 involving [5] 49/21 49/22 50/6 57/11 123/4 ipso [1] 135/12 Iqbal [2] 118/4 118/22 ironclad [1] 31/1 irrelevant [3] 6/6 49/23 54/20 is [823] is a [1] 116/19 is also [1] 143/4 is completely [1] 55/9 is on [1] 83/13 is worth [1] 23/18 isn't [4] 63/9 107/16 123/19 130/22 isolated [1] 126/18	issue [35] 4/21 10/8 12/12 14/9 15/1 17/10 17/24 21/18 29/23 31/6 36/7 42/14 52/9 67/6 67/9 67/12 68/24 69/12 69/24 71/15 79/3 79/5 86/6 103/19 106/23 131/12 133/3 146/18 146/24 147/9 153/2 156/16 159/18 160/12 160/17 issued [1] 108/8 issues [6] 34/15 71/25 81/1 82/14 86/19 149/25 it [437] it reviewed [1] 24/24 it's [13] 6/10 8/24 46/22 47/19 63/19 74/17 96/13 96/16 109/7 112/2 113/15 130/9 148/24 its [28] 5/1 5/2 5/15 6/11 24/20 26/13 28/6 29/19 41/8 44/7 44/19 56/17 61/11 63/12 76/1 76/8 76/8 83/24 84/4 85/9 86/25 99/1 99/7 103/15 103/18 104/25 108/21 128/7 itself [13] 11/22 39/23 64/6 65/16 102/7 108/16 109/6 131/1 137/3 137/7 144/9 145/8 160/12 J jail [2] 75/18 76/14 job [2] 56/11 96/18 JOHNSTON [9] 1/22 2/4 80/22 82/8 87/11 106/7 106/18 120/11 124/16 Johnston for [1] 120/11 join [1] 17/7 joined [2] 5/21 126/1 joining [1] 17/8 JPML [1] 85/17 JUDGE [6] 1/10 4/7 56/9 56/12 56/18 57/5 judgment [6] 56/22 63/4 119/6 119/24 120/2 139/2 judicial [1] 39/3 jumping [1] 83/9 juncture [1] 51/15 jurisdiction [1] 5/4 jurisdiction over [1] 5/4 jurisdictional [1] 5/14 jurisprudence [7] 13/20 14/18 14/21 16/3 18/1 25/12 29/24 jury [5] 24/24 25/1 30/3 39/16 104/21 just [95] 4/15 5/23 7/23 12/10 15/21 18/15 18/18 20/2 21/4 24/8 25/18 25/22 26/10 29/6 29/11 32/15 36/15 36/21 38/15 41/20 44/12 45/4 48/2 54/5 54/9 54/10 56/5 56/13 56/15 56/21 60/1 60/2 60/11 61/7 61/21 61/24 63/3 63/9 63/20 64/17 65/10 65/19 66/17 67/20 69/19 70/6 70/7 73/10 74/18 80/9 81/20 86/3 92/18 93/6 93/7 94/16 95/4 95/25 99/8 103/4 105/25 106/5 107/6 113/24 115/6	115/13 118/2 118/13 119/3 119/5 120/12 124/23 134/5 134/12 134/25 135/13 136/9 136/10 136/16 136/21 137/21 137/24 142/10 142/14 143/11 144/11 145/15 146/13 147/2 147/6 148/7 150/6 151/14 152/15 157/17 just at [1] 147/2 just look [1] 146/13 Justice [3] 33/21 75/11 96/22 Juul [1] 105/9 K KAPKE [10] 2/4 67/7 67/11 80/24 81/2 81/9 81/24 87/2 87/6 107/18 KAPLAN [10] 2/1 66/19 73/22 81/7 106/9 106/22 114/22 115/23 115/24 124/11 Kaplan's [2] 74/5 119/6 KARA [3] 2/4 80/24 87/6 Kaye [1] 1/16 keep [6] 32/16 34/3 43/6 67/20 139/21 161/10 Keeping [1] 52/19 keeps [1] 157/8 KELLER [74] 1/11 1/12 23/7 23/12 38/15 38/18 39/8 40/1 41/16 50/19 54/20 55/18 56/6 58/22 60/11 60/17 61/17 62/24 65/7 73/10 73/22 73/24 91/6 91/9 101/24 102/22 106/12 107/3 107/5 107/10 107/19 108/13 109/10 110/6 110/9 111/9 112/5 112/15 113/13 114/25 116/5 116/12 116/16 117/14 118/12 118/19 121/5 122/6 122/20 123/22 129/18 131/24 134/20 134/23 144/11 144/14 144/24 146/5 146/20 147/1 147/23 149/15 150/7 150/16 150/25 151/11 152/16 152/24 153/13 154/11 155/17 156/1 158/8 158/18 Keller explained [1] 101/24 Keller has [1] 54/20 Keller's [6] 91/2 101/4 101/21 120/20 133/16 156/14 kept [3] 46/11 49/10 121/7 key [7] 89/10 90/12 95/17 99/10 133/16 140/14 152/17 keyed [2] 65/11 65/20 kind [6] 101/1 125/15 132/14 132/25 133/16 160/6 kindly [1] 3/6 knew [1] 100/10 Knight [1] 1/19 know [34] 7/10 23/1 24/5 24/13 24/13 50/21 51/5 54/19 56/15 62/3 67/13 76/10 77/19 77/22 80/20 81/21 82/12 84/12 95/12 106/12 107/24 109/16 112/1 115/14 118/15 118/17 123/10 125/4 134/5 139/7 147/20 149/17 158/16 161/1
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---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

K know if [1] 107/24 knowing [2] 87/25 94/19 knowingly [4] 89/3 89/9 90/3 90/22 knowledge [4] 76/25 83/19 83/23 111/18 known [1] 24/19 knows [4] 6/7 43/15 78/8 134/1	83/12 later [4] 20/16 61/7 69/13 161/15 law [298] law and [2] 27/24 65/18 law can't [1] 63/11 law of [1] 41/19 law prevents [1] 145/23 law to [1] 139/24 lawfully [1] 24/6 lawnmower [1] 85/11 laws [10] 15/3 15/6 25/14 47/11 57/2 60/20 148/16 149/13 153/17 159/23 lawsuits [1] 15/13 lead [4] 7/18 117/4 132/24 133/13 leads [1] 84/5 leap [1] 153/5 learned [2] 41/8 61/11 least [10] 10/15 37/12 64/2 70/25 98/25 113/18 131/25 138/25 158/21 158/22 leave [6] 37/12 59/21 80/8 125/13 134/18 145/12 leaves [1] 29/21 leaving [2] 95/14 123/7 ledger [2] 28/2 114/1 leech [1] 2/13 left [19] 8/6 8/7 30/1 62/8 77/20 81/15 81/16 81/25 95/2 125/17 129/7 133/5 133/11 133/25 143/24 151/24 152/1 152/3 152/6 legal [3] 31/22 52/15 72/10 legally [1] 36/16 legions [1] 132/10 legislature [1] 85/9 legislatures [1] 97/19 legitimate [1] 98/8 length [5] 5/23 52/1 55/6 79/6 146/2 lengthy [2] 73/14 116/5 Lenkner [1] 1/12 less [3] 19/17 51/6 132/12 lesser [1] 42/11 lesson [1] 76/4 let [25] 7/10 12/15 13/24 24/23 25/11 46/1 55/20 58/8 67/23 80/20 81/21 82/2 89/7 95/1 96/1 105/25 110/12 125/4 129/16 130/11 134/5 138/19 143/23 146/13 158/8 let's [16] 8/7 27/17 28/3 29/8 31/3 34/19 35/9 57/11 60/1 92/12 92/13 98/16 106/11 112/6 112/7 140/10 lets [2] 45/19 149/23 letter [4] 116/17 117/1 117/3 117/5 level [6] 13/7 50/4 57/22 69/3 89/21 119/20 levels [6] 77/14 82/24 115/5 115/13 116/15 119/14 Levine [3] 36/7 139/8 139/20 liabilities [1] 76/2 liability [116] 1/5 3/3 4/22 5/6 5/21 6/7 9/4 9/8 12/18	12/24 19/24 24/18 25/6 25/7 29/6 30/10 37/5 43/18 45/19 48/9 50/10 53/14 53/19 53/20 58/19 58/21 59/4 59/5 60/23 61/3 71/5 71/8 71/9 71/10 71/11 71/14 71/17 71/19 75/12 76/19 77/4 82/25 83/4 83/5 84/24 85/7 85/19 86/12 93/18 95/2 95/8 95/10 95/12 95/13 95/14 95/16 95/18 96/11 97/2 97/3 97/4 98/3 98/12 101/13 102/4 102/4 102/6 102/8 102/13 102/13 102/20 102/21 107/8 107/12 107/13 107/17 109/10 109/15 109/23 110/2 111/17 126/22 126/25 133/15 135/23 136/13 140/12 140/18 140/20 141/2 141/6 141/11 141/14 141/18 141/19 144/23 144/24 145/4 145/4 145/5 145/6 145/11 150/24 153/23 153/24 154/4 154/9 154/23 155/12 158/16 159/7 159/24 160/2 160/4 160/8 160/20 liability survive [1] 50/10 liable [9] 43/9 50/15 68/20 83/7 83/7 86/16 96/21 109/12 113/8 light [9] 30/7 78/14 96/2 96/3 96/14 132/8 135/20 139/17 157/13 light that [1] 139/17 like [44] 4/10 6/22 8/24 11/7 14/1 23/13 23/17 26/6 30/2 30/13 32/6 32/15 33/9 34/16 49/17 57/2 60/20 67/4 68/4 68/5 71/1 76/4 78/14 84/13 86/24 92/8 96/4 96/24 97/3 97/11 97/11 98/3 98/7 101/3 115/6 116/1 125/4 125/11 125/13 139/13 142/1 147/15 148/22 159/15 limitations [2] 50/7 133/2 limited [4] 5/7 7/20 51/1 76/8 limiting [1] 104/6 line [9] 16/17 17/25 18/17 19/15 32/21 44/24 117/7 141/2 158/24 list [3] 110/19 146/1 146/3 listed [2] 35/6 35/13 listen [2] 37/23 97/23 listening [1] 161/3 lists [1] 110/13 litigation [9] 1/5 3/3 3/25 6/24 62/22 66/21 85/17 86/19 141/8 litigations [1] 86/24 little [13] 17/9 35/11 54/7 65/10 95/3 101/10 114/4 133/10 133/13 137/14 138/7 154/1 154/4 LLC [4] 1/12 4/24 5/10 5/12 LLP [7] 1/16 1/19 1/22 2/1 2/5 2/9 2/13 locate [1] 100/3 lock [1] 60/25
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

L lodge [1] 33/19 logic [3] 64/3 96/22 142/8 logical [3] 31/22 33/2 153/5 logically [1] 53/8 long [7] 28/20 41/9 47/21 133/18 135/11 148/20 161/2 longer [1] 24/10 look [28] 10/25 11/5 19/6 42/21 53/8 57/11 58/10 58/12 58/20 76/20 88/7 88/11 90/8 114/14 130/21 131/2 131/4 131/12 132/18 136/16 140/17 141/3 145/3 146/13 148/22 159/8 160/3 161/14 looked [9] 18/3 54/14 54/22 73/14 96/7 120/23 149/19 159/16 160/5 looking [5] 15/5 121/12 158/24 159/6 159/23 loophole [4] 13/13 13/24 17/25 70/5 Los [2] 1/20 1/24 lose [3] 143/7 154/15 155/13 loss [7] 7/16 69/10 153/14 154/4 154/7 158/11 160/9 lot [8] 51/3 51/6 57/5 68/18 74/4 82/16 92/21 113/19 lots [1] 46/20 low [2] 47/13 49/5 lower [1] 29/22 luminaries [1] 96/22 lump [1] 74/2 lunch [3] 66/9 66/10 80/7 luncheon [1] 80/12	major changes [1] 42/7 majority [4] 21/18 128/1 133/9 159/24 make [51] 19/17 20/7 22/16 27/13 29/10 31/11 31/25 32/24 34/15 35/7 35/19 37/10 43/1 43/11 43/13 49/17 55/25 62/4 65/15 66/2 76/10 79/13 81/11 83/16 93/3 94/11 94/21 96/17 97/9 99/8 101/20 103/2 107/11 108/3 108/16 117/15 118/6 121/22 123/16 137/11 139/10 139/19 143/12 146/13 147/6 155/22 156/2 156/10 156/11 157/12 159/19 makes [16] 19/18 27/5 31/1 43/12 64/12 80/9 100/19 101/10 103/14 104/9 104/14 130/12 140/19 141/25 153/5 159/21 making [13] 6/15 21/14 24/10 36/3 36/4 41/17 44/21 48/17 62/15 64/13 136/2 148/18 159/4 management [1] 161/12 mandated [1] 112/24 mandatory [1] 137/11 manner [6] 14/7 28/8 151/20 156/9 161/10 161/11 manual [3] 38/24 39/3 141/8 manufacture [4] 19/15 28/13 68/2 85/13 manufactured [3] 5/22 68/23 101/17 manufacturer [47] 5/21 6/9 9/3 9/7 10/4 17/15 17/20 18/5 29/1 40/16 40/25 41/8 41/25 42/4 43/13 43/16 44/6 44/7 47/6 48/8 48/25 53/14 54/15 54/22 55/4 56/16 61/11 61/12 66/3 68/20 73/17 83/15 89/2 89/8 89/14 90/22 100/10 101/18 107/22 107/25 128/20 150/11 150/18 150/19 151/18 157/11 157/13 manufacturer discovered [1] 47/6 manufacturer's [3] 34/13 44/2 127/18 manufacturers [59] 6/9 7/3 7/14 8/23 9/1 9/16 9/23 10/17 11/3 16/22 19/1 21/4 29/15 32/15 33/5 34/3 34/9 34/17 35/1 36/8 39/19 42/9 52/11 53/4 57/1 59/8 59/12 61/23 63/15 64/3 65/14 68/13 70/10 74/19 78/21 83/5 85/12 86/6 88/25 89/24 90/21 91/15 92/24 95/16 95/19 95/20 95/21 101/15 108/15 109/3 111/4 125/9 132/2 134/16 136/4 136/7 138/24 139/21 157/20 manufacturers had [1] 57/1 manufacturers' [3] 8/17 9/17 52/3 manufacturing [19] 4/24 5/5 5/10 5/11 11/3 12/3 20/1	20/6 20/10 43/23 44/24 45/12 46/21 46/23 46/25 90/2 130/16 131/14 133/3 many [9] 56/20 57/16 57/23 136/22 148/17 148/19 158/17 161/2 161/14 marched [1] 140/4 market [12] 2/9 23/25 24/11 41/14 44/25 47/25 57/4 61/16 108/15 109/2 132/8 151/19 market or [1] 109/2 Massachusetts [7] 5/1 5/3 5/3 5/5 5/12 5/20 6/4 massive [1] 85/17 master [22] 4/23 23/19 45/6 46/6 46/9 60/9 69/2 77/12 83/9 83/21 85/1 85/2 92/19 93/16 114/8 116/12 123/24 124/13 145/25 146/3 146/6 149/22 match [3] 9/17 35/12 148/8 matches [1] 28/15 matching [2] 26/20 147/5 material [1] 47/7 materials [2] 51/8 77/18 matter [29] 4/10 4/14 6/12 11/7 12/22 28/19 34/10 36/13 44/9 47/17 52/6 53/7 53/23 56/22 76/24 76/25 77/1 125/13 135/13 137/2 137/3 140/6 141/24 142/7 150/25 155/20 156/17 156/24 162/2 matters [3] 3/5 34/15 161/16 maximalist [1] 41/25 maximum [1] 81/24 may [42] 3/14 8/16 16/8 23/9 23/11 42/14 48/21 57/9 60/1 60/2 63/1 64/17 66/8 67/24 70/18 80/6 82/6 87/4 87/8 91/25 99/13 104/12 104/16 110/11 114/22 120/8 121/4 123/12 125/20 125/24 136/21 147/15 148/20 149/14 150/2 150/4 150/5 151/10 153/17 155/14 157/5 158/7 maybe [9] 17/1 35/4 36/13 92/11 92/11 97/21 123/20 139/5 152/21 md [2] 1/3 2/14 MDL [11] 3/3 11/21 17/22 24/19 24/20 123/23 127/3 133/22 140/25 141/24 159/18 MDLs [4] 83/4 86/24 124/1 141/8 me [35] 4/2 6/23 7/10 12/15 22/10 23/8 23/8 25/11 46/1 55/20 58/8 61/7 73/1 80/20 80/23 81/20 89/7 91/20 95/1 96/1 98/3 102/5 105/25 110/12 125/4 125/9 125/22 129/16 130/11 136/21 138/19 143/23 146/13 153/10 158/8 mean [9] 36/23 46/9 46/11 46/13 46/14 108/8 142/11 142/15 143/12 mean you [1] 142/15 meaning [5] 43/3 65/2 99/7 99/25 100/22
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>M</p> <p>meaningful [1] 30/6</p> <p>meaningless [1] 18/15</p> <p>meaningless with [1] 18/15</p> <p>means [17] 15/9 32/9 37/25 38/6 49/9 68/15 84/15 85/16 87/25 88/10 93/14 98/4 99/21 106/16 127/23 145/22 154/21</p> <p>meant [1] 122/24</p> <p>measure [1] 132/7</p> <p>measures [1] 104/5</p> <p>meat [1] 24/8</p> <p>medical [20] 14/19 15/1 15/5 15/8 16/5 16/14 16/16 17/1 30/19 30/24 31/4 31/24 49/20 51/24 57/12 68/6 90/13 131/10 131/11 142/19</p> <p>Medical Device [1] 30/24</p> <p>medication [4] 126/9 127/18 128/6 128/19</p> <p>medications [1] 128/8</p> <p>medicine [2] 10/12 66/20</p> <p>Medtronic [3] 32/5 55/24 60/21</p> <p>meet [5] 31/21 70/3 91/24 109/7 148/22</p> <p>meeting [1] 80/8</p> <p>meets [4] 25/2 53/17 108/20 137/5</p> <p>member [1] 5/2</p> <p>memorandum [4] 7/4 66/13 80/16 124/25</p> <p>mens [1] 75/12</p> <p>Mensing [51] 8/19 10/2 10/13 10/22 12/17 12/24 13/9 13/13 13/19 14/9 14/11 16/6 16/10 16/20 18/10 18/14 20/13 21/7 22/12 22/19 26/7 34/7 34/8 42/6 43/15 50/6 50/10 52/2 52/7 52/9 53/3 53/24 54/17 55/2 55/13 58/6 69/4 69/23 70/2 70/24 71/3 71/23 72/12 79/20 82/14 84/18 86/5 86/25 101/23 124/1 128/16</p> <p>Mensing's [1] 11/9</p> <p>mention [1] 69/12</p> <p>mentioned [2] 57/21 115/7</p> <p>merchantability [4] 63/25 64/7 65/2 73/2</p> <p>merchantable [1] 73/3</p> <p>mere [3] 29/16 118/23 119/5</p> <p>merely [8] 15/7 71/12 103/23 104/22 118/4 127/17 128/23 143/11</p> <p>Meridian [1] 2/5</p> <p>met [4] 78/15 141/15 142/3 142/6</p> <p>Metal [1] 90/15</p> <p>mic [1] 54/8</p> <p>microphone [1] 152/21</p> <p>Middle [1] 50/3</p> <p>might [15] 8/2 11/14 26/24 35/16 55/8 55/21 56/21 67/13 93/9 119/6 133/1 133/13 142/24 154/2 160/11</p> <p>milestone [1] 23/24</p> <p>millions [2] 24/2 24/2</p>	<p>Mills [4] 131/7 140/15 159/15 159/15</p> <p>mind [7] 24/18 28/10 43/6 52/19 60/24 67/21 125/18</p> <p>mine [1] 143/13</p> <p>minimal [1] 83/13</p> <p>minimum [1] 59/21</p> <p>Mink [9] 26/23 32/23 48/15 59/1 59/21 92/9 138/10 144/14 144/15</p> <p>Mink and [1] 138/10</p> <p>Minnesota [1] 97/11</p> <p>minority [1] 160/14</p> <p>minute [2] 23/5 54/5</p> <p>minutes [28] 7/7 7/7 7/15 8/2 8/5 8/6 8/9 20/19 66/24 67/4 67/11 74/1 80/18 81/15 81/16 81/18 81/18 81/19 81/24 91/4 103/11 125/1 125/12 125/14 125/17 134/6 134/19 134/21</p> <p>Miriam [1] 100/1</p> <p>mirrors [1] 31/5</p> <p>misbranded [26] 16/24 25/3 28/5 28/6 28/14 28/16 28/20 28/22 58/2 75/8 75/24 76/24 89/9 89/15 89/17 89/17 90/3 90/23 108/19 108/20 111/19 112/1 128/8 132/4 135/19 146/11</p> <p>misbranding [86] 17/4 17/10 17/14 17/17 17/19 23/14 23/16 25/3 25/5 26/18 26/18 27/17 28/11 28/25 29/5 30/12 45/2 62/6 74/7 74/11 74/14 77/6 79/5 101/5 101/10 101/19 108/22 109/8 111/13 111/15 111/16 124/3 126/9 126/11 128/4 129/5 129/12 130/2 130/10 130/17 130/20 130/23 130/25 131/18 132/12 132/15 134/24 135/3 135/5 135/7 135/13 136/1 136/5 136/8 136/13 136/17 136/18 137/2 137/3 137/6 137/8 137/12 140/2 143/25 144/3 144/4 144/7 145/25 146/4 146/21 146/25 147/10 147/21 147/22 147/25 148/5 148/11 148/12 149/8 150/8 151/16 151/17 152/4 152/7 153/6 155/1</p> <p>mischaracterization [3] 130/1 130/8 130/9</p> <p>mischaracterizing [1] 135/3</p> <p>misheard [1] 136/21</p> <p>misleading [1] 28/6</p> <p>misplaced [1] 50/6</p> <p>missed [1] 8/2</p> <p>misses [1] 153/1</p> <p>missing [1] 110/16</p> <p>Mississippi [1] 32/6</p> <p>misstate [1] 126/8</p> <p>mistake [1] 24/24</p> <p>mistaken [2] 30/25 130/1</p> <p>moderate [1] 36/5</p> <p>modifies [1] 103/3</p> <p>modify [2] 85/9 134/17</p>	<p>modifying [1] 99/21</p> <p>molecular [1] 84/4</p> <p>molecule [18] 9/18 9/20 11/18 11/18 11/22 11/25 36/23 37/3 42/6 91/14 92/3 92/7 93/2 94/4 113/20 132/20 132/21 138/14</p> <p>molecule is [1] 11/18</p> <p>moment [7] 4/3 15/21 21/4 23/17 44/24 107/5 109/14</p> <p>moments [1] 30/15</p> <p>money [2] 77/1 155/10</p> <p>month [3] 40/5 40/7 40/14</p> <p>months [2] 40/10 77/24</p> <p>Moore [5] 26/6 27/16 56/8 72/15 76/4</p> <p>moot [2] 124/10 124/15</p> <p>more [30] 16/14 17/9 34/22 51/6 51/14 57/23 59/22 63/5 65/15 70/15 83/1 85/10 89/11 90/4 90/10 90/12 90/18 90/21 90/23 94/16 95/25 97/3 98/1 107/3 109/2 114/14 119/7 131/9 141/1 150/2</p> <p>more than [1] 90/21</p> <p>Moreno [1] 53/6</p> <p>morning [14] 2/1 3/1 4/13 4/16 6/16 7/2 7/13 8/16 23/7 23/11 66/16 79/25 106/1 106/14</p> <p>Morris [2] 18/20 54/24</p> <p>Moss [30] 20/17 20/22 20/24 21/9 21/10 21/12 21/20 21/23 62/10 62/12 63/10 63/12 63/16 64/1 64/6 64/8 64/11 64/12 64/16 64/20 65/25 69/17 71/24 72/3 72/7 72/17 72/20 72/23 73/8 73/13</p> <p>most [14] 3/8 3/17 22/21 32/8 35/13 41/24 41/25 61/9 66/7 69/24 83/10 95/19 160/1 161/7</p> <p>most respects [1] 35/13</p> <p>motion [56] 5/22 6/6 6/11 6/12 7/1 7/3 8/17 13/16 17/7 37/15 37/16 37/16 37/17 37/18 38/25 39/4 42/21 57/8 62/12 62/20 66/5 66/10 66/12 66/22 67/16 67/18 67/18 74/6 80/15 81/2 81/14 84/21 97/13 102/12 106/4 106/5 106/6 121/1 123/25 124/8 124/9 124/15 124/22 124/24 125/8 125/10 129/13 133/14 137/18 145/17 145/17 145/18 145/18 145/19 150/2 160/22</p> <p>motions [19] 1/9 3/2 6/19 22/25 68/22 80/3 105/21 106/1 106/2 106/3 120/22 124/7 124/10 126/13 134/2 137/23 160/23 161/9 161/17</p> <p>motivate [1] 104/22</p> <p>mouse [2] 55/7 57/2</p> <p>mouth [1] 157/8</p> <p>move [10] 12/15 21/1 46/1 63/16 137/25 138/24 153/11 155/4 155/19 155/20</p> <p>moving [2] 63/21 161/10</p>
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M	137/21 137/21 148/1 151/12 151/23 157/7 157/8 158/4 myself [1] 60/25	157/20 new and [1] 32/17 next [7] 33/5 33/19 66/10 76/20 126/23 127/2 147/8 nice [2] 80/7 161/19 night [1] 95/3 nine [3] 10/13 13/5 81/24 Ninth [2] 32/21 33/10 no [91] 1/3 9/19 11/7 12/12 12/12 12/13 12/13 15/13 15/20 16/2 16/15 17/4 19/22 19/25 24/9 24/10 25/4 29/6 29/17 30/20 31/19 32/10 33/16 35/14 35/24 36/10 36/14 41/19 41/19 42/4 42/19 47/1 47/18 47/22 50/8 53/23 56/20 60/19 70/5 70/13 75/4 75/5 75/5 76/18 84/16 85/9 85/15 93/3 93/14 94/4 95/11 96/6 96/12 98/10 98/18 99/12 102/19 103/9 103/19 107/7 107/12 107/20 108/4 110/6 117/7 121/19 123/6 127/23 128/6 128/21 129/13 132/5 132/6 136/9 136/19 137/2 137/10 137/19 140/6 142/6 143/9 144/2 145/3 145/10 146/14 148/9 148/9 148/9 155/10 156/16 160/18 no deviation [1] 9/19 nobody [5] 27/20 95/22 96/15 96/19 135/17 noise [2] 15/23 83/25 non [3] 49/18 49/19 84/15 non-drug [1] 49/18 non-implied [1] 49/19 nonderivative [1] 85/15 none [4] 28/17 100/6 100/16 160/6 nonetheless [3] 97/6 108/18 142/6 nonidentical [3] 69/15 156/25 157/3 nonparallel [1] 154/19 nonstarters [1] 86/7 normal [6] 11/20 45/17 68/9 93/15 118/2 133/22 not [281] not because [1] 24/8 not conceding [2] 156/3 156/17 not foreclose [1] 64/22 not knowingly [1] 89/9 not make [1] 155/22 not reflect [1] 71/11 note [9] 55/22 72/24 73/10 97/17 135/24 140/14 154/25 155/22 160/9 noted [6] 71/17 75/10 78/2 108/21 114/13 149/3 nothing [10] 16/14 30/2 96/25 98/2 98/9 108/3 111/15 120/24 122/8 134/11 notice [2] 39/3 83/11 noticed [1] 119/12 noting [3] 63/15 113/15 138/23 notion [1] 55/6
MPIC [1] 115/1 Mr [71] 4/11 4/16 4/22 7/15 7/17 7/21 7/23 8/5 8/6 8/8 15/21 20/16 21/2 34/20 36/2 36/12 37/20 38/15 54/4 54/11 54/19 55/20 56/6 60/11 73/10 73/21 73/22 74/5 81/7 83/9 91/2 91/6 101/4 101/21 101/23 102/22 106/12 107/3 107/5 109/9 110/8 112/4 114/24 115/23 116/5 116/12 116/16 117/14 118/12 119/6 120/20 122/5 123/22 129/18 131/24 133/16 134/20 144/11 144/14 144/24 146/5 150/7 150/16 150/25 152/15 152/24 153/13 155/17 156/1 156/14 158/8 Mrs. [1] 3/22 Mrs. Stipes [1] 3/22 Ms [5] 40/2 69/13 87/11 134/7 152/20 Ms. [21] 3/8 4/1 17/5 67/7 67/11 69/13 81/2 81/9 81/24 87/2 97/10 107/18 110/7 125/12 126/1 126/4 129/3 129/11 143/22 152/23 156/9 Ms. Eisenstein [5] 17/5 69/13 126/1 143/22 152/23 Ms. Eisenstein's [1] 126/4 Ms. Goldenberg [1] 97/10 Ms. Horton [3] 125/12 129/3 129/11 Ms. Kapke [7] 67/7 67/11 81/2 81/9 81/24 87/2 107/18 Ms. Stipes [4] 3/8 4/1 110/7 156/9 much [19] 23/2 23/3 45/9 45/11 45/13 49/15 51/3 79/24 109/11 110/10 115/19 119/8 119/9 124/18 131/9 132/12 132/23 152/22 161/19 multi [1] 159/18 multi-state [1] 159/18 multiple [8] 26/6 26/23 27/21 54/14 55/22 59/2 98/22 134/15 must [26] 5/7 21/3 21/6 21/10 22/11 22/20 25/23 27/12 27/25 40/5 40/6 44/25 62/13 71/23 72/3 72/7 75/7 88/7 89/20 90/8 110/14 110/15 112/2 112/17 112/17 117/9 must allege [1] 5/7 muted [1] 15/23 Mutual [1] 8/20 my [49] 3/18 4/20 5/9 7/15 14/1 29/12 30/15 31/10 31/15 39/25 41/18 44/20 49/20 59/3 59/21 65/9 67/3 67/10 73/19 74/1 75/20 77/9 80/24 81/23 82/16 87/11 91/1 95/9 98/14 99/4 99/10 100/18 102/22 103/10 113/9 125/9 126/1 126/3 135/2 135/4 136/20	N name [5] 3/15 37/11 38/16 39/13 39/17 named [3] 68/4 69/1 123/23 narrow [8] 100/17 103/1 126/18 126/24 127/21 133/15 148/24 152/6 narrowed [1] 134/3 narrower [6] 27/13 93/17 122/3 138/5 138/13 142/23 narrower and [1] 27/13 national [1] 25/8 nature [2] 11/22 159/4 NDA [18] 6/8 6/10 35/18 38/25 68/4 70/11 70/13 70/17 72/9 79/14 84/15 91/13 108/25 126/10 131/1 131/4 131/13 136/11 NDA and [1] 136/11 NDAs [1] 22/16 NDMA [30] 19/18 20/8 24/15 42/22 42/23 43/10 44/9 45/10 51/3 51/4 51/13 77/14 78/3 83/23 84/5 112/25 113/17 114/16 115/5 115/14 115/19 116/15 117/4 117/15 119/5 119/9 119/14 122/12 122/14 137/10 NDMA-laced [1] 122/14 near [1] 67/3 necessarily [9] 45/10 60/12 63/3 88/10 88/17 92/2 97/6 107/15 122/18 necessary [5] 59/24 69/19 82/1 82/10 88/20 necessitate [1] 68/16 need [22] 3/20 8/12 21/9 26/12 35/16 51/14 54/15 54/23 58/10 74/1 77/18 81/24 81/25 98/12 99/23 109/17 139/9 139/19 144/25 150/6 152/5 154/22 needed [1] 9/7 needs [3] 53/15 96/16 138/5 negligence [14] 57/14 57/14 57/24 57/24 61/4 71/9 77/8 78/7 78/9 78/19 92/24 93/8 112/22 122/10 negligent [8] 18/25 59/5 59/5 59/16 59/17 60/23 108/1 109/19 neither [4] 68/20 71/18 136/14 136/15 never [15] 6/9 10/11 11/3 12/6 17/14 25/2 83/3 84/13 93/11 101/25 136/25 137/12 151/22 152/9 152/12 nevertheless [2] 91/23 110/12 new [21] 1/17 11/2 24/11 25/1 27/24 30/6 32/6 32/17 52/6 104/1 104/1 135/19 137/4 138/15 139/17 139/22 149/2 149/18 152/8 157/12	

N notions [1] 130/25 notwithstanding [1] 25/15 novel [3] 48/17 86/13 86/17 November [1] 99/12 November 7 [1] 99/12 novo [1] 29/23 now [23] 4/10 6/19 20/17 48/12 80/2 84/12 84/24 86/13 91/6 102/11 103/4 103/14 103/20 109/5 116/6 119/20 123/17 124/21 134/3 136/11 137/22 156/13 160/23 nowhere [2] 135/15 135/23 nuances [1] 141/22 nullity [1] 18/14 nullity and [1] 18/14 number [7] 3/4 12/1 12/2 20/23 51/23 52/2 88/6 numerous [3] 22/21 49/2 49/24 NW [1] 2/2 NY [1] 1/17	80/13 82/2 82/4 82/6 100/25 105/20 105/25 106/11 107/1 108/6 109/9 110/8 122/5 124/18 134/20 145/21 160/21 omit [1] 104/23 omitted [1] 99/10 on first [1] 29/24 on limitations [1] 50/7 on negligence [1] 71/9 once [30] 27/2 27/19 32/2 32/19 34/7 34/20 34/22 45/8 46/24 48/2 56/5 62/8 74/11 75/3 76/3 77/16 78/1 95/24 98/16 99/22 100/20 111/21 121/6 121/20 121/23 140/6 149/24 150/2 151/12 154/25 one [71] 2/9 2/13 4/10 4/15 5/5 11/24 12/1 12/21 13/3 13/22 14/4 15/21 18/20 19/14 20/23 23/21 27/21 31/17 31/23 32/10 32/24 33/22 40/20 40/23 41/25 45/21 47/2 47/2 49/21 49/21 49/22 51/23 54/2 55/23 56/12 60/20 61/8 61/22 66/9 70/15 71/18 79/8 84/2 86/24 98/14 109/17 110/5 116/24 116/25 119/3 120/14 122/16 124/2 124/3 129/17 129/20 131/23 133/15 141/18 142/6 142/19 145/15 148/16 148/17 148/20 149/18 152/13 158/19 158/21 159/1 159/18 one-year [1] 19/14 ones [13] 9/25 31/9 32/13 35/22 48/4 60/24 91/23 94/10 95/21 115/6 121/13 140/23 141/13 ongoing [1] 117/6 only [57] 3/12 9/25 15/3 18/5 21/22 21/25 22/15 22/24 26/23 26/25 27/8 31/8 34/9 35/25 41/22 45/19 50/23 63/12 65/12 69/1 70/11 70/16 71/4 83/18 87/11 87/24 87/25 90/1 90/16 93/12 93/20 95/10 96/9 100/19 101/13 104/5 104/9 105/7 117/3 120/15 121/9 121/12 122/7 123/4 126/11 136/8 138/10 140/21 141/12 141/25 143/4 144/16 146/11 146/17 146/22 152/25 154/17 open [9] 29/21 30/1 62/9 143/24 151/24 152/1 152/3 152/6 152/13 open in [1] 152/6 opening [6] 8/2 35/2 36/14 148/1 151/23 152/7 operate [2] 93/18 103/23 opinion [4] 16/7 16/10 33/21 104/25 opportunity [3] 60/15 61/7 64/18 opposed [3] 35/25 95/16 157/24 opposite [3] 136/10 150/9 151/17	opposition [21] 22/25 34/21 35/9 42/21 43/1 46/4 49/19 49/23 51/20 60/6 62/18 64/15 85/5 85/6 85/21 86/10 87/22 103/11 120/13 120/22 146/10 oppositions [1] 121/24 option [1] 157/21 optional [1] 104/22 or assistance [1] 42/5 oral [4] 141/20 142/3 161/6 161/17 order [7] 21/1 28/4 78/16 92/6 126/19 139/10 142/21 orders [1] 161/9 ordinary [3] 99/7 99/24 100/22 origin [1] 100/4 original [3] 35/16 35/22 94/7 OTC [4] 17/6 31/5 69/11 131/5 other [79] 5/20 19/8 21/20 27/10 28/14 28/21 32/6 33/24 39/23 45/25 48/16 50/8 52/23 53/24 56/12 57/12 60/3 60/24 61/1 61/25 62/7 63/1 63/17 63/18 65/2 67/20 73/16 73/16 76/16 78/13 83/20 84/7 85/14 92/8 94/2 94/6 97/9 101/25 102/1 108/7 111/8 111/15 113/25 114/1 115/6 122/14 123/3 126/17 127/19 129/21 130/19 130/23 132/7 135/3 136/1 136/2 136/3 136/15 138/8 139/25 140/9 143/2 143/13 144/4 144/8 146/19 146/24 147/3 147/4 147/15 148/14 149/9 151/12 153/14 156/2 157/2 159/2 159/17 161/16 other provision [1] 111/15 others [5] 93/24 97/11 115/2 140/16 142/12 otherwise [11] 21/14 62/15 64/14 68/6 68/8 68/11 77/9 110/21 127/12 150/18 153/18 our [75] 3/8 8/21 14/2 14/9 16/4 18/13 20/15 23/14 24/18 25/3 25/5 26/17 27/17 30/2 30/11 31/1 33/3 33/23 34/5 34/8 34/15 35/9 36/13 36/14 42/21 44/23 45/24 46/18 50/24 55/22 59/17 62/5 62/8 63/22 66/10 76/9 77/5 77/8 85/22 91/12 93/9 94/7 94/24 97/13 100/6 100/16 101/4 101/23 111/10 112/22 112/22 113/23 113/24 114/17 120/22 124/12 131/8 137/16 138/12 138/24 140/2 143/2 143/9 147/18 151/22 152/11 152/11 155/4 155/7 155/11 159/3 159/14 160/23 161/17 161/18 ours [1] 30/21 ourselves [1] 92/13 out [29] 3/7 6/22 16/10 18/2 20/2 20/9 23/18 44/1 50/2 53/12 57/21 57/21 59/22
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

O out... [16] 61/23 63/9 65/21 76/7 81/1 85/21 86/21 92/13 93/12 100/18 119/23 135/22 140/13 141/13 147/16 153/22 outcome [2] 159/19 159/22 outcomes [2] 16/9 16/12 outcomes across [1] 16/12 outset [1] 138/23 outside [12] 65/20 106/24 111/21 116/8 119/18 120/24 123/7 123/18 123/19 123/20 133/2 154/12 over [28] 5/4 8/7 13/5 24/14 32/25 51/3 54/9 68/18 74/8 82/13 82/16 92/15 101/15 109/11 110/2 120/14 127/6 127/8 127/11 128/12 135/1 138/19 152/12 152/21 153/15 154/22 160/24 161/4 over-the-counter [8] 92/15 127/6 127/8 127/11 128/12 135/1 138/19 153/15 overall [1] 59/18 overarching [1] 49/17 overcome [1] 13/18 overheated [1] 122/11 overlap [2] 67/4 74/4 overriding [1] 16/19 overstate [1] 29/12 overview [1] 126/4 owed [6] 51/21 52/14 52/21 54/12 56/4 60/7 own [9] 44/7 44/11 46/12 92/19 93/16 130/1 130/9 141/23 159/14	154/21 154/25 157/9 paralleled [1] 144/17 parameters [1] 48/25 parenthetical [3] 99/16 99/21 103/3 Park [1] 1/23 part [21] 5/18 5/23 6/1 6/3 29/20 38/9 38/13 43/14 51/12 56/6 68/22 81/23 83/19 87/23 103/2 103/3 104/25 110/12 113/19 114/19 129/6 partial [1] 124/24 partially [1] 41/21 participant [1] 15/22 participated [1] 11/3 participating [1] 161/3 particular [18] 6/6 28/7 45/11 61/9 62/2 100/13 104/7 107/3 113/21 119/17 119/17 129/19 130/3 150/3 153/12 155/3 155/9 159/17 particularly [5] 82/13 85/1 86/18 86/22 107/25 parties [5] 6/20 6/22 14/5 39/2 102/20 partners [1] 90/2 parts [1] 87/18 party [4] 32/8 33/9 90/2 146/8 pass [1] 73/17 passed [1] 97/12 passing [1] 95/3 passthrough [1] 68/12 past [7] 13/5 28/21 68/18 119/22 138/7 151/12 160/25 Patheon [12] 4/24 5/4 5/10 5/11 5/18 5/19 5/22 6/1 6/2 6/4 6/9 6/11 Patheon's [1] 5/15 patience [1] 161/4 patient [1] 100/13 pattern [1] 24/21 pauline [5] 2/17 3/8 3/10 4/9 162/5 pause [1] 78/23 pay [9] 29/17 30/20 36/14 70/7 75/18 96/25 97/7 97/22 98/2 pay to [1] 97/7 payment [1] 109/19 payor [1] 146/8 penal [1] 76/13 penalties [4] 75/16 75/22 104/2 147/17 Pennsylvania [3] 2/2 32/6 109/21 penultimate [1] 33/20 people [3] 19/19 80/10 161/2 per [3] 57/14 57/24 160/2 percent [1] 136/23 perfect [3] 3/17 3/25 84/20 perfectly [7] 20/7 33/18 62/7 98/8 100/10 123/12 123/13 perform [1] 10/24 performing [1] 42/2 perhaps [5] 61/7 74/5 131/15 133/2 133/3	period [9] 12/13 39/12 39/17 40/6 40/7 40/14 75/8 81/21 123/8 period than [1] 39/12 periods [1] 77/21 permissible [2] 117/22 118/3 permission [4] 36/9 42/5 91/16 139/10 permit [6] 110/2 153/24 154/3 154/7 158/10 158/14 permitted [3] 49/11 68/3 158/12 person [1] 78/9 personal [16] 4/23 5/4 22/7 45/6 46/6 69/2 77/12 109/20 114/8 116/13 124/14 127/21 127/24 128/13 146/6 149/22 persuaded [1] 97/18 persuasive [1] 28/18 pertain [2] 82/18 110/25 pertaining [1] 7/16 Petrosinelli [1] 83/10 Pfizer [1] 52/17 pharmaceutical [4] 8/20 68/13 78/12 83/4 pharmaceuticals [3] 68/3 70/23 116/18 pharmacies [18] 67/8 71/2 83/7 87/7 87/12 87/16 88/3 88/19 88/24 89/7 89/11 89/16 89/22 89/23 90/20 101/11 101/24 102/1 pharmacist [1] 100/12 pharmacy [14] 67/5 67/16 79/4 80/15 80/23 80/24 81/4 82/8 83/15 85/8 101/6 101/17 106/8 124/9 phase [2] 119/22 150/1 Philadelphia [1] 2/10 phon [2] 75/10 142/14 phrase [1] 73/1 phrased [1] 26/12 phraseology [3] 26/15 95/6 148/3 physical [1] 127/22 PI [2] 83/21 85/2 pick [1] 156/10 picked [1] 137/17 pickup [1] 122/17 picture [1] 23/18 piece [1] 160/18 Pierce [1] 2/18 Pierce/West [1] 2/18 pill [2] 19/11 19/20 PIN [1] 103/25 Piper [1] 2/9 place [6] 5/2 5/16 12/7 16/2 89/5 130/19 placement [1] 71/5 places [2] 91/11 139/21 plain [5] 76/8 98/24 99/24 136/17 136/19 Plaintiff [22] 23/4 27/6 37/24 38/11 40/8 43/17 44/14 50/14 57/24 66/15 72/3 92/18 93/6 93/16 93/20 93/24 113/5 117/9 118/10 119/22 120/17 144/15
P PA [1] 2/10 package [1] 44/10 packaging [5] 41/11 47/4 78/21 96/5 127/19 page [11] 42/25 43/2 46/4 50/11 62/18 64/15 85/6 85/11 136/10 147/8 154/2 pages [4] 51/19 60/5 62/11 146/10 paid [1] 77/1 PALM [3] 1/2 1/5 2/18 papers [3] 55/22 74/22 77/10 paperwork [1] 123/15 paperwork that [1] 123/15 paragraph [20] 4/23 22/6 33/21 75/23 77/11 83/21 114/9 114/25 115/2 115/2 116/5 116/12 116/17 119/3 120/14 120/14 120/15 120/21 146/6 146/8 paragraphs [3] 45/5 88/5 115/6 parallel [33] 14/19 15/7 15/9 15/9 15/12 15/13 16/2 16/24 16/25 17/3 17/10 17/14 17/17 17/19 26/2 30/11 30/13 30/17 30/23 32/20 32/25 50/9 101/10 128/3 139/25 140/11 142/4 147/22 148/12 148/21		

P	political [1] 99/13	prejudice [2] 68/17 128/25
Plaintiff's [2] 45/11 53/16	Porter [1] 1/16	premarket [2] 131/12 131/14
PLAINTIFFS [167]	portion [5] 105/1 115/20	premise [6] 14/11 17/19
Plaintiffs' [45] 5/6 9/4	152/17 152/19 152/25	18/23 69/25 131/18 131/20
11/24 13/2 13/18 17/14 18/18	pose [7] 4/14 29/15 31/15	premised [2] 57/15 72/14
21/2 22/24 36/17 37/19 42/16	46/17 104/1 105/24 110/12	preparation [1] 161/5
43/1 43/5 50/5 52/15 62/12	posed [2] 106/13 143/24	prepare [1] 161/8
68/15 68/16 71/4 86/15 87/22	posit [1] 119/21	prepared [1] 41/18
88/18 89/10 89/13 89/15 90/3	position [11] 18/13 32/13	prescribed [1] 151/21
91/2 101/10 103/13 104/18	34/21 54/20 62/8 107/24	prescription [9] 44/3 44/5
104/23 105/13 111/2 111/5	111/2 111/5 111/10 137/21	69/16 87/13 87/17 88/25
118/7 120/13 120/21 122/8	157/11	92/15 107/25 128/12
124/24 128/25 129/14 130/23	positions [1] 153/11	prescriptions [1] 68/7
131/18 153/20	positive [1] 136/23	presence [1] 117/4
plan [1] 8/7	possession [1] 111/25	present [3] 11/8 13/9 110/14
planks [1] 133/16	possibility [2] 52/11 53/5	presentation [15] 3/6 3/7
plausible [16] 46/18 50/15	possible [8] 3/17 3/24 30/9	3/16 3/20 3/21 23/5 36/12
50/24 51/7 78/4 114/14	80/9 91/10 118/5 137/20	67/15 67/17 74/8 78/24 107/5
114/17 115/13 115/19 116/19	156/24	133/16 146/2 161/6
117/9 117/16 118/6 118/8	post [5] 23/20 35/17 42/4	presentations [5] 3/12 3/13
119/7 119/14	123/25 123/25	66/6 80/4 110/11
plausibly [2] 117/13 123/17	posture [6] 45/16 46/22	presented [3] 13/2 13/7
play [1] 129/7	50/25 63/5 63/23 78/5	160/24
played [2] 33/6 57/3	potential [2] 60/7 84/23	presenters [1] 3/6
plays [1] 116/19	potentially [5] 40/9 47/11	presenting [3] 30/4 87/6
Plaza [1] 1/12	48/7 83/7 88/4	161/3
plead [11] 27/6 45/21 45/22	practice [2] 98/8 150/2	presumably [1] 117/25
45/23 92/23 92/24 92/25 94/6	pre [1] 20/13	presume [1] 150/22
94/14 115/17 123/17	pre-approval [1] 20/13	presumption [2] 104/10
pleaded [8] 27/12 77/19	precaution [1] 59/17	132/13
93/25 116/10 118/25 121/20	precautionary [1] 132/7	pretending [1] 76/12
121/23 137/5	precautions [5] 59/9 139/3	prevail [2] 102/9 141/12
pleading [6] 44/20 44/22	139/7 139/14 157/14	prevent [7] 12/4 43/4 54/15
45/9 77/16 82/23 94/18	precedent [4] 69/4 105/7	54/23 55/11 78/19 91/23
pleadings [1] 13/12	128/16 149/17	prevents [4] 38/1 38/7
pleads [1] 116/2	precedent in [1] 128/16	106/17 145/23
please [8] 4/8 8/16 15/23	precise [3] 24/21 25/8 84/19	previous [2] 65/9 158/9
23/11 38/4 38/17 67/24 87/8	precisely [4] 9/16 46/8	previously [4] 72/8 87/9
pled [5] 71/18 94/7 119/23	52/20 113/17	137/21 152/9
144/15 158/17	preclude [2] 73/13 141/18	price [7] 24/1 127/14 130/5
plexiglass [1] 4/4	predicate [2] 11/23 20/25	154/8 158/15 159/7 160/12
PLIVA [4] 8/19 18/20 18/21	predictions [1] 159/4	primarily [5] 17/6 21/21
52/7	preempt [3] 105/13 123/4	25/20 33/25 101/6
PLIVER [1] 54/25	143/9	primary [2] 48/11 139/21
plus [2] 68/18 81/18	preempted [61] 9/9 10/6	principal [2] 5/2 5/16
point [44] 16/6 18/2 18/13	12/22 13/11 15/4 15/8 18/18	principle [6] 14/13 48/12
19/17 19/22 20/2 20/9 21/12	19/7 20/2 20/13 21/3 21/6	72/2 72/13 84/18 103/16
30/19 32/23 41/17 48/17	22/11 31/6 40/7 40/10 44/2	principles [24] 11/14 22/19
49/17 54/2 56/13 60/8 62/16	48/7 49/1 52/15 52/22 54/17	23/13 23/14 25/11 27/17
74/5 74/25 76/11 77/7 77/11	60/8 69/19 70/5 70/10 70/24	29/22 29/24 49/25 54/17
90/5 98/10 98/14 111/24	71/15 74/15 76/3 82/19 84/8	55/13 55/24 56/21 70/24 71/2
113/4 113/14 114/3 114/8	84/19 87/17 90/4 90/19 90/25	87/1 92/18 93/15 95/13 97/24
114/23 119/7 122/11 136/24	105/3 106/25 112/19 116/10	98/1 98/20 113/24 114/6
137/14 138/8 140/14 141/13	121/15 124/7 124/25 126/3	prior [3] 104/2 105/13 139/9
143/10 144/11 150/16 155/15	126/22 127/15 129/22 131/22	private [1] 76/12
157/5 161/8	133/10 138/2 139/15 144/13	probably [4] 8/8 8/9 81/23
pointed [7] 92/8 100/18	144/22 151/7 153/15 153/21	113/19
116/5 119/2 130/18 145/3	154/10 155/24 156/19 156/19	probative [1] 137/8
145/9	preemption [212]	problem [5] 5/25 56/24 57/7
pointing [1] 116/12	preemption by [1] 128/2	57/8 130/23
points [11] 16/10 17/12	Preemption doesn't [1] 93/18	problems [1] 133/1
20/23 48/21 56/5 62/23	preemptive [10] 16/12 18/12	procedural [6] 45/15 46/21
104/23 134/25 137/15 141/9	27/19 55/12 87/10 114/6	50/24 63/5 63/23 78/5
147/13	133/18 133/23 133/24 134/13	proceed [16] 12/19 20/17
policies [1] 25/8	preempts [7] 69/10 69/15	23/10 46/22 66/1 82/6 92/3
policy [5] 30/9 96/23 97/7	87/24 90/9 90/24 110/23	93/5 122/3 125/18 125/20
97/24 98/11	127/7	125/24 134/16 137/24 138/6
	prefers [1] 109/1	152/8

<p>P</p> <p>proceeding [4] 76/12 78/19 86/5 161/18</p> <p>proceeding if [1] 78/19</p> <p>proceedings [2] 119/22 162/2</p> <p>process [9] 12/3 36/1 43/23 45/12 46/23 47/1 79/9 108/24 133/8</p> <p>processes [1] 89/5</p> <p>produce [1] 13/16</p> <p>produced [1] 122/12</p> <p>product [105] 5/22 6/8 6/10 11/4 11/15 12/17 13/12 19/1 19/3 19/14 19/15 19/18 19/22 20/7 27/22 28/1 41/3 44/19 45/10 47/3 47/4 47/6 47/15 49/9 49/10 51/10 58/3 58/18 61/3 64/5 65/3 68/13 68/24 70/6 73/17 78/12 78/17 79/17 83/4 85/15 85/19 86/12 88/20 88/21 89/4 89/9 89/15 90/3 96/19 101/16 102/7 102/18 107/18 107/24 108/2 109/24 112/3 116/7 117/4 117/16 122/7 122/9 122/12 122/19 123/10 123/13 130/12 131/19 135/12 136/12 140/4 140/12 140/18 140/20 141/2 141/6 141/11 141/14 141/18 144/1 144/10 144/23 144/23 145/4 145/4 145/5 145/6 145/7 145/10 149/1 149/5 151/15 153/23 153/24 154/4 154/8 158/16 159/7 159/24 160/2 160/4 160/7 160/11 160/15 160/20</p> <p>products [35] 1/5 3/3 22/14 46/12 49/5 51/2 51/6 51/13 63/2 64/21 68/10 69/11 73/3 73/16 77/15 78/22 87/24 88/9 88/13 88/22 95/22 99/14 99/22 100/9 103/5 109/20 109/23 110/2 111/11 113/1 114/16 119/13 127/11 154/23 155/12</p> <p>products' [1] 73/5</p> <p>profile [6] 20/11 30/5 32/18 43/24 44/4 46/17</p> <p>profit [1] 24/10</p> <p>profoundly [1] 30/25</p> <p>program [1] 16/16</p> <p>prohibit [1] 128/19</p> <p>prohibits [3] 9/6 69/20 105/17</p> <p>promise [1] 24/9</p> <p>promises [2] 65/3 73/4</p> <p>promotes [1] 25/7</p> <p>promptly [1] 19/12</p> <p>prone [2] 19/11 19/19</p> <p>prong [1] 90/5</p> <p>pronunciation [1] 3/15</p> <p>proof [2] 111/21 137/7</p> <p>propensity [1] 11/25</p> <p>proper [5] 72/20 72/22 78/6 103/15 107/16</p> <p>property [1] 127/23</p> <p>proposition [6] 33/16 48/17</p>	<p>62/25 92/9 120/5 135/16</p> <p>propositions [2] 136/14 147/4</p> <p>prospectively [1] 104/6</p> <p>protect [1] 97/1</p> <p>prove [6] 27/6 102/10 102/15 102/15 109/17 109/24</p> <p>proved [1] 27/12</p> <p>proven [1] 119/6</p> <p>proves [1] 33/3</p> <p>provide [7] 14/17 27/13 55/4 62/3 89/1 117/1 126/4</p> <p>provided [2] 89/21 158/14</p> <p>provider [1] 98/6</p> <p>providers [2] 58/1 96/24</p> <p>provides [3] 15/3 21/13 49/7</p> <p>providing [2] 52/5 55/6</p> <p>provision [25] 28/11 35/15 36/2 36/6 50/8 63/8 63/9 63/12 69/8 75/4 98/19 99/9 101/13 104/8 105/4 111/14 111/15 129/16 137/11 138/19 144/4 144/6 147/11 156/22 157/4</p> <p>provision of [1] 144/6</p> <p>provisions [6] 29/5 35/18 90/13 94/11 111/13 123/3</p> <p>provisions as [1] 35/18</p> <p>prudent [3] 74/2 78/9 78/11</p> <p>public [5] 97/7 97/23 98/11 115/18 115/18</p> <p>pull [6] 29/1 108/15 109/2 136/22 137/9 151/18</p> <p>pull Ranitidine [1] 137/9</p> <p>pulled [1] 44/25</p> <p>punishments [1] 76/6</p> <p>punitive [1] 104/5</p> <p>purchase [4] 127/14 154/8 158/15 159/7</p> <p>pure [3] 18/6 18/6 110/21</p> <p>purely [2] 160/10 160/14</p> <p>purity [5] 20/11 40/13 43/24 44/4 46/16</p> <p>purported [1] 128/4</p> <p>purportedly [1] 57/15</p> <p>purpose [1] 85/17</p> <p>purposes [22] 25/19 26/20 45/20 67/20 74/3 85/5 97/16 102/12 136/3 138/25 139/2 143/5 143/8 146/21 147/2 147/13 147/18 148/25 149/11 149/22 156/7 161/17</p> <p>pursuant [5] 60/20 113/11 115/10 153/15 153/16</p> <p>pursue [7] 74/12 92/21 93/7 93/7 93/17 137/20 138/18</p> <p>pursued [1] 138/2</p> <p>pursuing [4] 83/11 95/10 140/12 152/1</p> <p>put [15] 3/16 41/2 42/3 48/12 53/7 59/14 77/24 78/14 78/21 83/10 84/21 95/25 136/17 150/13 160/8</p> <p>putative [1] 127/5</p> <p>puts [2] 95/22 145/10</p> <p>putting [1] 157/8</p>	<p>Q</p> <p>qualities [1] 40/13</p> <p>quality [4] 20/11 40/13 43/23 46/16</p> <p>quantities [1] 24/14</p> <p>quarantine [1] 88/4</p> <p>quarantining [1] 88/21</p> <p>question [69] 3/14 4/12 4/15 4/20 4/23 5/9 5/11 6/14 29/15 29/21 31/10 31/15 32/17 33/18 37/13 37/23 38/4 38/22 39/10 41/12 41/17 43/16 46/2 47/10 50/14 50/19 53/2 58/8 58/24 60/2 60/4 61/14 61/19 62/8 64/10 64/18 81/7 81/13 100/23 105/3 105/25 106/12 106/19 110/5 110/6 110/8 110/12 112/4 114/9 118/12 120/2 122/18 122/22 123/6 124/5 136/25 143/24 148/9 148/23 151/24 152/3 152/6 152/13 153/12 153/13 154/5 156/20 158/9 158/9</p> <p>question already [1] 53/2</p> <p>questioning [2] 124/20 160/22</p> <p>questions [19] 7/18 7/24 20/16 37/7 41/15 45/15 50/5 66/6 67/14 67/18 80/6 87/5 105/19 105/22 105/24 107/3 109/22 145/13 145/15</p> <p>quick [2] 90/5 122/21</p> <p>quickly [2] 23/21 74/11</p> <p>quintessential [1] 109/14</p> <p>quite [6] 28/12 29/6 31/5 95/9 96/21 119/14</p> <p>quote [11] 11/7 34/9 52/5 52/6 52/6 85/6 85/12 87/24 103/22 105/12 105/17</p> <p>quoted [5] 135/4 135/6 135/17 136/1 151/13</p> <p>R</p> <p>RACHEL [3] 2/8 125/9 125/25</p> <p>raise [1] 94/10</p> <p>raised [3] 60/9 134/25 153/2</p> <p>raises [1] 30/14</p> <p>raising [1] 156/15</p> <p>ramifications [1] 30/25</p> <p>range [18] 47/9 47/13 47/21 47/22 49/5 49/8 49/13 49/15 49/15 112/8 112/9 112/10 112/20 117/18 117/24 118/1 119/18 121/14</p> <p>ranges [13] 77/22 78/13 112/24 113/22 116/9 117/22 120/1 120/3 121/17 123/11 123/18 123/19 123/21</p> <p>ranges is [1] 123/21</p> <p>ranging [1] 144/18</p> <p>RANITIDINE [63] 1/4 9/18 9/22 11/15 11/22 12/6 24/3 24/5 24/8 24/14 25/2 30/8 36/18 39/14 39/21 39/23 42/3 42/23 44/24 45/8 45/22 46/11 49/8 51/2 51/5 51/12 57/4</p>
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>R</p> <p>RANITIDINE... [36] 69/11 69/16 77/20 77/25 84/12 84/14 84/17 85/4 85/9 87/17 88/1 88/25 91/14 92/3 92/19 100/7 100/9 101/17 102/2 102/10 102/11 108/19 111/11 112/25 114/16 115/19 116/14 119/4 119/8 119/13 123/7 128/15 132/21 137/9 144/20 155/24</p> <p>rarely [1] 87/12</p> <p>rate [1] 78/3</p> <p>rate through [1] 78/3</p> <p>RE [5] 1/4 3/3 49/3 104/13 105/9</p> <p>rea [1] 75/12</p> <p>reach [4] 23/24 145/6 152/18 153/1</p> <p>react [1] 121/25</p> <p>read [10] 13/2 63/8 65/19 76/1 96/6 99/9 116/21 152/16 152/18 152/24</p> <p>reading [4] 10/21 14/2 59/21 103/3</p> <p>reaffirm [1] 32/23</p> <p>real [2] 5/25 31/17</p> <p>reality [1] 13/11</p> <p>really [17] 10/25 11/1 18/14 20/6 43/7 43/8 44/21 47/17 89/10 102/23 129/7 130/2 132/16 134/9 156/1 159/17 159/19</p> <p>realm [2] 133/8 134/12</p> <p>reason [12] 3/11 16/25 17/23 19/25 27/14 51/25 70/22 84/19 96/21 119/15 143/2 156/23</p> <p>reasonable [2] 45/18 45/24</p> <p>reasonably [3] 12/13 78/9 78/11</p> <p>reasons [8] 51/5 71/22 73/8 82/21 84/7 97/7 103/12 142/17</p> <p>rebuffed [1] 58/7</p> <p>rebuttal [18] 7/19 7/20 8/3 8/8 78/25 81/21 82/1 82/3 82/4 87/4 91/1 91/5 101/2 103/14 125/14 125/19 134/19 143/20</p> <p>rebuttals [1] 28/17</p> <p>rebutting [1] 147/13</p> <p>recall [14] 31/3 91/25 108/8 108/16 108/23 108/24 109/5 132/1 132/2 132/11 132/13 137/2 137/7 137/11</p> <p>receive [2] 28/13 111/20</p> <p>received [2] 6/20 111/24</p> <p>receiving [1] 112/2</p> <p>recently [1] 22/21</p> <p>recess [1] 80/12</p> <p>recitals [1] 118/24</p> <p>recklessly [1] 5/8</p> <p>recognize [14] 13/11 32/5 33/8 51/20 56/2 63/23 97/5 137/23 147/20 153/7 154/14 155/5 155/10 160/13</p>	<p>recognize the [1] 33/8</p> <p>recognized [4] 52/20 84/22 86/17 144/12</p> <p>recognizes [5] 5/6 16/7 95/20 101/14 160/19</p> <p>recognizing [3] 42/17 114/1 149/7</p> <p>recollection [1] 120/20</p> <p>recommended [1] 151/21</p> <p>record [13] 3/17 3/23 4/20 7/10 23/6 37/11 37/20 115/18 115/18 125/4 146/5 156/11 162/2</p> <p>recording [1] 156/8</p> <p>recordkeeping [1] 99/19</p> <p>recoverable [1] 160/11</p> <p>recovery [4] 154/7 158/10 158/15 159/7</p> <p>recurred [1] 141/20</p> <p>redesign [11] 19/3 19/3 42/6 85/8 91/14 92/3 93/14 94/4 96/14 128/19 138/14</p> <p>redesigned [4] 41/13 47/24 61/16 93/2</p> <p>redress [1] 76/16</p> <p>reducing [1] 47/8</p> <p>redundant [2] 128/23 134/10</p> <p>reference [8] 3/15 22/24 35/6 35/13 63/17 90/16 92/12 136/4</p> <p>referenced [5] 107/14 109/15 110/15 116/16 153/22</p> <p>references [2] 3/23 75/22</p> <p>referencing [1] 97/4</p> <p>referred [4] 4/25 9/12 111/14 160/10</p> <p>referring [3] 55/6 82/9 146/23</p> <p>refers [1] 141/7</p> <p>reflect [1] 71/11</p> <p>Reframing [1] 14/7</p> <p>refund [11] 127/7 130/5 145/5 145/5 145/8 145/10 154/8 158/16 160/6 160/12 160/18</p> <p>refunds [2] 127/5 153/14</p> <p>refusal [1] 111/8</p> <p>refuse [2] 110/15 110/20</p> <p>refuse to [1] 110/20</p> <p>refused [4] 111/3 111/6 111/7 111/10</p> <p>refute [1] 131/23</p> <p>Regal [1] 76/4</p> <p>regard [4] 42/16 141/10 149/1 155/6</p> <p>regarding [2] 101/4 158/10</p> <p>regardless [3] 88/7 109/25 111/11</p> <p>regime [10] 35/8 40/17 44/17 71/8 71/11 73/12 95/14 95/19 97/3 99/3</p> <p>Register [3] 29/2 32/14 135/10</p> <p>regulated [5] 63/3 63/10 64/22 65/17 85/13</p> <p>regulation [4] 31/6 34/2 72/20 139/8</p> <p>regulations [7] 39/18 39/20</p>	<p>40/11 43/11 92/16 94/10 128/19</p> <p>regulatory [7] 25/8 35/8 44/17 48/8 130/19 132/1 132/14</p> <p>rehash [1] 79/6</p> <p>Rehnquist's [1] 33/21</p> <p>reimagine [1] 53/24</p> <p>rein [1] 93/10</p> <p>reject [3] 19/7 19/25 152/4</p> <p>rejected [14] 13/6 14/10 14/13 14/14 17/24 18/10 28/24 30/5 57/18 71/6 126/20 135/16 150/10 150/15</p> <p>rejecting [1] 151/13</p> <p>relate [1] 87/20</p> <p>related [10] 16/23 43/23 43/24 64/21 69/11 69/20 83/12 85/3 117/21 151/1</p> <p>relatedly [1] 113/9</p> <p>relates [7] 8/22 15/16 17/6 17/12 90/7 101/13 110/9</p> <p>relating [8] 46/4 64/16 64/23 87/16 88/16 99/19 99/20 127/10</p> <p>relationship [2] 5/23 65/22</p> <p>released [1] 113/21</p> <p>relevant [9] 20/9 25/20 33/22 61/9 97/15 97/16 115/3 147/12 147/15</p> <p>reliance [1] 49/18</p> <p>reliant [1] 49/20</p> <p>relied [1] 159/10</p> <p>relitigate [1] 104/19</p> <p>rely [4] 33/23 48/11 51/24 158/23</p> <p>relying [4] 3/13 102/21 114/25 141/2</p> <p>remain [4] 93/24 94/17 94/25 126/24</p> <p>remainder [3] 91/1 94/24 126/25</p> <p>remaining [9] 4/15 8/10 67/10 81/8 81/17 91/3 91/5 94/17 124/15</p> <p>remains [2] 33/17 74/15</p> <p>remarks [3] 41/18 135/4 148/1</p> <p>remedies [2] 76/6 76/22</p> <p>remedy [1] 112/2</p> <p>remember [2] 12/10 38/16</p> <p>remembering [1] 77/16</p> <p>remind [5] 17/8 18/19 19/10 42/25 95/4</p> <p>reminded [1] 148/2</p> <p>reminds [1] 41/22</p> <p>remotely [1] 160/19</p> <p>removal [3] 41/13 47/24 61/16</p> <p>remove [2] 95/24 132/8</p> <p>removed [2] 70/15 79/8</p> <p>render [1] 86/25</p> <p>renders [1] 103/18</p> <p>repackager [2] 7/17 22/9</p> <p>repackagers [6] 7/3 21/6 22/10 22/13 22/17 22/19</p> <p>repackaging [1] 47/9</p> <p>reparatory [1] 17/3</p>
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>R</p> <p>repealed [2] 34/1 34/2</p> <p>repeat [5] 4/7 38/4 69/24 74/7 89/7</p> <p>repeated [3] 73/1 105/7 120/21</p> <p>repeatedly [1] 26/17</p> <p>repertory [3] 16/8 16/13 16/16</p> <p>repetitive [1] 154/2</p> <p>replead [3] 59/22 118/11 158/12</p> <p>repleading [2] 59/25 158/14</p> <p>replete [1] 45/3</p> <p>reply [10] 34/22 36/11 101/4 101/9 104/13 136/5 136/7 136/10 140/22 147/14</p> <p>report [1] 58/1</p> <p>reporter [4] 2/17 3/9 162/5 162/6</p> <p>reporting [1] 133/4</p> <p>represent [3] 5/14 66/19 125/7</p> <p>representing [1] 6/3</p> <p>represents [1] 67/8</p> <p>request [1] 4/6</p> <p>requests [1] 67/3</p> <p>require [21] 9/2 31/12 39/16 41/13 42/8 47/23 48/1 49/4 52/24 61/15 75/12 89/11 89/22 89/24 90/4 90/20 109/6 112/6 119/21 121/8 142/21</p> <p>required [19] 10/4 36/22 37/2 70/12 79/16 88/19 90/1 95/5 98/25 108/24 110/3 116/11 116/20 116/23 117/17 120/4 121/11 150/23 157/15</p> <p>requirement [17] 26/12 26/13 26/14 47/20 47/21 87/21 88/16 90/6 90/7 90/19 110/20 111/18 131/15 153/1 157/1 157/3 158/3</p> <p>requirements [54] 8/25 27/13 69/16 79/10 87/19 87/20 88/11 88/13 88/23 89/6 90/10 90/11 90/16 93/3 95/5 99/14 99/17 103/5 103/6 104/12 104/16 104/20 104/21 104/25 105/6 105/16 110/24 116/3 116/23 117/14 117/23 126/7 126/10 127/12 129/20 129/21 129/22 129/24 130/22 130/22 130/25 131/3 131/4 131/12 131/16 131/16 131/17 131/21 132/17 132/25 133/4 144/8 153/19 157/23</p> <p>requires [17] 9/15 9/19 19/6 20/12 20/25 21/19 29/1 31/11 41/25 43/25 45/1 89/2 109/8 123/16 129/20 139/16 151/18</p> <p>requiring [4] 34/2 41/3 137/1 157/13</p> <p>reserve [7] 61/7 66/25 67/4 73/19 79/2 81/25 91/1</p> <p>reserved [2] 67/11 139/1</p> <p>residence [1] 6/11</p> <p>resorted [1] 134/10</p>	<p>respect [31] 16/9 17/15 18/15 29/18 32/1 33/6 33/10 63/2 65/14 72/1 75/1 84/11 88/14 88/23 92/14 94/1 94/13 94/24 99/17 103/7 106/11 107/23 129/19 130/4 132/6 140/1 141/4 151/3 154/24 155/2 155/3</p> <p>respectfully [1] 119/21</p> <p>respects [1] 35/13</p> <p>respond [17] 48/21 55/16 57/9 60/16 85/22 91/7 105/9 114/23 116/1 120/8 121/3 137/16 143/7 150/4 150/7 151/8 155/14</p> <p>respondent's [1] 71/7</p> <p>responding [1] 7/18</p> <p>response [15] 22/24 44/14 55/20 71/4 87/23 101/21 101/23 103/9 104/18 128/21 136/25 140/21 146/13 154/3 156/14</p> <p>responses [2] 91/2 91/3</p> <p>responsibilities [9] 27/1 28/3 42/11 91/22 93/23 95/23 100/15 121/8 140/8</p> <p>responsibility [9] 9/22 28/15 42/2 48/4 61/24 74/24 121/16 121/18 139/21</p> <p>responsible [2] 77/14 95/21</p> <p>rest [7] 8/5 33/24 34/5 73/19 84/24 148/25 161/20</p> <p>restrictive [1] 105/15</p> <p>result [9] 16/9 19/17 45/13 75/25 118/2 122/15 150/20 151/5 151/6</p> <p>resulted [2] 115/4 116/15</p> <p>results [1] 51/4</p> <p>resume [2] 80/1 80/2</p> <p>resurrects [1] 91/19</p> <p>retailer [29] 22/25 67/5 67/16 73/18 74/6 78/5 78/24 79/3 80/14 80/23 80/24 81/4 82/8 82/18 83/17 84/9 85/8 85/10 86/12 106/8 107/23 108/3 108/7 108/9 109/23 112/6 120/11 122/14 124/9</p> <p>retailers [57] 51/11 67/8 68/14 71/1 74/3 74/9 74/19 74/21 75/9 75/21 76/23 77/23 78/16 78/20 82/10 82/21 83/6 83/18 83/19 83/20 83/22 84/10 84/12 84/13 84/15 85/3 85/13 86/7 86/15 92/5 92/25 93/8 94/2 95/8 95/15 95/23 96/24 97/2 97/5 97/8 98/5 100/7 101/6 101/11 101/24 102/1 106/19 107/8 107/15 108/14 109/3 109/12 111/6 112/23 123/23 124/6 124/16</p> <p>retailers' [1] 97/12</p> <p>retread [1] 82/16</p> <p>retroactivity [5] 103/11 103/12 103/13 103/19 104/10</p> <p>retroactivity because [1] 103/12</p> <p>retrospectively [1] 103/23</p> <p>return [3] 25/11 44/20 98/20</p>	<p>returns [1] 121/6</p> <p>review [2] 22/1 96/17</p> <p>reviewed [1] 24/24</p> <p>reviewing [1] 90/21</p> <p>revised [1] 6/20</p> <p>revisit [2] 74/6 91/20</p> <p>revisiting [1] 82/17</p> <p>rewarded [1] 86/20</p> <p>RICHARD [1] 2/12</p> <p>Rick [1] 7/13</p> <p>rife [1] 132/18</p> <p>right [22] 4/3 6/13 8/12 8/15 20/21 44/18 48/20 57/5 66/4 81/13 97/23 97/25 103/4 107/20 107/21 109/5 119/20 119/25 124/18 125/20 155/10 160/21</p> <p>rights [1] 139/1</p> <p>rise [1] 130/17</p> <p>risk [6] 43/10 44/10 46/17 71/12 83/23 84/6</p> <p>risks [1] 96/19</p> <p>Riverside [1] 1/12</p> <p>road [1] 53/17</p> <p>ROBIN [2] 1/9 2/17</p> <p>robust [1] 131/9</p> <p>Rodenticide [2] 90/15 105/5</p> <p>Roget's [1] 100/4</p> <p>role [3] 68/1 68/14 98/6</p> <p>room [5] 7/21 29/8 49/9 116/8 120/19</p> <p>root [1] 117/5</p> <p>ROSENBERG [3] 1/3 1/9 2/17</p> <p>roughly [1] 81/25</p> <p>round [7] 97/13 124/7 134/1 134/3 145/15 150/1 161/17</p> <p>route [1] 108/23</p> <p>rubber [1] 53/17</p> <p>rubric [1] 106/24</p> <p>rule [22] 7/3 21/22 26/8 27/14 27/15 37/16 37/17 45/17 62/19 66/12 80/15 105/13 105/14 106/4 118/10 119/16 119/21 121/23 124/7 124/9 124/23 145/18</p> <p>rules [2] 35/21 98/12</p> <p>ruling [3] 50/10 57/22 62/21</p> <p>run [6] 13/13 29/10 29/25 36/11 71/6 82/2</p> <p>runs [2] 18/10 62/5</p> <p>S</p> <p>safe [5] 12/12 12/14 19/14 24/8 42/19</p> <p>safer [6] 19/18 52/10 52/12 53/3 53/5 53/15</p> <p>safety [7] 30/5 32/18 43/24 64/4 77/2 132/20 143/25</p> <p>said [49] 3/12 16/7 18/4 25/22 26/6 29/13 33/6 33/8 34/9 35/3 36/4 41/2 47/3 50/14 54/4 54/11 64/17 79/7 80/3 85/16 92/1 97/10 98/7 98/22 99/4 102/5 104/11 105/22 107/3 107/7 112/17 120/21 122/23 136/21 136/25 137/2 137/21 142/13 144/12 144/12 148/5 150/7 150/9</p>
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>S</p> <p>said... [6] 150/21 150/25 151/22 152/5 153/3 155/17</p> <p>sale [2] 18/25 109/13</p> <p>sales [1] 23/23</p> <p>same [61] 14/14 16/25 20/4 21/5 24/25 26/2 26/10 26/14 27/25 29/3 29/11 30/4 31/9 31/12 31/25 32/13 33/13 34/5 35/1 35/18 35/22 36/6 36/12 37/23 38/21 40/19 40/21 40/22 59/2 59/13 64/3 67/7 70/12 70/12 71/2 73/1 74/16 77/23 81/25 83/16 84/7 89/18 92/11 92/20 95/6 96/4 97/10 97/25 105/25 108/3 129/22 130/7 139/15 140/5 141/10 142/5 145/15 148/3 149/19 154/9 156/9</p> <p>sameness [12] 9/12 9/14 9/19 10/6 20/2 20/4 21/17 35/3 35/10 35/10 35/24 53/21</p> <p>samples [1] 117/15</p> <p>Sanofi [13] 4/25 5/10 5/14 5/18 5/19 5/19 5/20 5/22 5/24 6/1 6/2 6/3 125/7</p> <p>SARAH [8] 1/22 2/4 80/22 82/7 106/7 106/18 120/11 124/16</p> <p>satisfied [10] 41/10 41/19 41/21 47/8 61/12 61/21 78/15 94/22 94/23 108/22</p> <p>satisfied by [1] 41/21</p> <p>satisfies [1] 56/17</p> <p>satisfy [4] 47/11 47/12 118/22 150/22</p> <p>save [2] 126/25 134/18</p> <p>saved [1] 127/20</p> <p>saving [7] 100/18 100/19 100/21 138/21 140/10 140/19 154/13</p> <p>savings [10] 88/12 127/22 141/13 144/24 145/2 154/18 154/22 155/8 155/9 160/1</p> <p>saw [2] 25/2 123/4</p> <p>say [66] 10/20 10/21 10/25 12/23 13/21 19/6 19/9 19/16 19/18 23/1 24/3 28/19 29/15 30/16 30/19 30/20 34/7 35/2 35/4 35/12 36/16 38/16 45/8 45/9 45/11 45/12 45/14 45/18 48/13 54/11 61/7 73/10 74/10 74/22 75/25 85/12 93/2 93/9 93/12 98/1 98/9 109/1 112/6 112/7 112/16 115/4 115/23 117/5 119/16 122/25 122/25 128/22 130/19 132/24 133/1 136/7 136/9 136/11 137/5 137/16 139/19 140/16 140/22 142/10 154/3 154/14</p> <p>say that [1] 154/3</p> <p>saying [18] 14/8 28/25 29/23 36/13 43/8 44/23 111/25 115/8 119/4 120/6 135/21 138/1 138/14 143/11 151/25 157/8 157/24 157/25</p> <p>says [41] 29/3 31/13 31/13</p>	<p>32/12 33/22 34/16 34/25 35/16 47/15 47/17 49/14 56/13 59/16 74/12 75/22 76/5 77/12 95/9 98/11 99/12 99/19 103/5 114/4 114/5 117/3 118/23 120/13 120/14 120/24 135/11 135/18 140/20 141/3 144/24 150/12 150/12 150/21 151/17 152/17 155/10 159/4</p> <p>says the [1] 140/20</p> <p>scenario [1] 158/13</p> <p>schedule [2] 6/20 161/12</p> <p>scheme [6] 17/3 25/8 34/6 48/8 71/17 136/16</p> <p>schemes [2] 16/8 16/13</p> <p>Scholer [1] 1/16</p> <p>School [1] 103/17</p> <p>science [6] 30/3 30/6 32/17 34/3 139/17 139/22</p> <p>science and [1] 139/22</p> <p>scientific [4] 5/2 24/25 45/15 137/4</p> <p>scientifically [3] 24/11 135/19 152/8</p> <p>scientists [1] 96/17</p> <p>scope [7] 6/12 29/19 76/8 87/10 88/17 105/4 133/22</p> <p>score [4] 18/11 45/25 95/4 157/19</p> <p>scratch [1] 93/9</p> <p>screen [5] 23/4 78/23 80/5 91/7 105/22</p> <p>screwed [1] 96/7</p> <p>se [3] 57/14 57/24 160/2</p> <p>SEAN [2] 2/12 54/1</p> <p>search [1] 159/2</p> <p>second [16] 3/2 9/3 17/14 21/12 26/22 30/3 69/8 83/1 87/19 90/5 97/13 104/9 105/1 110/1 114/9 124/7</p> <p>second-guess [1] 30/3</p> <p>Secondly [1] 20/6</p> <p>seconds [6] 20/20 81/15 81/16 81/19 81/19 91/5</p> <p>section [43] 15/3 21/12 21/19 28/7 28/9 28/12 59/10 59/17 62/14 64/12 65/4 69/8 74/20 75/3 75/14 75/14 75/15 75/16 75/21 76/20 76/21 99/12 101/12 110/17 111/1 116/25 123/1 127/9 127/21 130/12 139/3 139/7 146/4 146/11 146/14 146/17 147/9 147/16 147/17 153/16 153/21 157/14 159/10</p> <p>sections [2] 146/22 147/15</p> <p>Securities [1] 81/3</p> <p>Security [17] 67/6 69/14 87/3 87/8 87/10 87/14 88/8 90/9 90/24 98/15 102/25 103/21 110/10 110/13 110/23 122/6 122/24</p> <p>see [26] 4/18 7/6 23/8 23/9 23/18 26/5 31/3 37/13 51/2 60/1 60/12 80/10 95/17 106/11 116/4 118/10 125/21 125/23 125/24 129/21 133/11 133/24 134/2 147/14 154/18</p>	<p>160/8</p> <p>seeing [2] 121/20 161/14</p> <p>seek [13] 53/13 76/22 89/11 89/13 90/4 110/24 111/23 126/19 127/5 127/7 128/2 130/4 155/10</p> <p>seeking [3] 76/14 76/15 150/22</p> <p>seeks [1] 129/13</p> <p>seem [2] 98/18 135/25</p> <p>seems [1] 84/22</p> <p>seen [2] 11/10 115/14</p> <p>segue [1] 31/24</p> <p>seize [2] 76/24 111/23</p> <p>sell [16] 19/1 27/21 28/1 28/16 28/20 75/7 102/6 102/17 102/19 102/23 107/17 108/7 108/10 130/7 130/12 149/1</p> <p>seller [2] 97/12 97/25</p> <p>sellers [1] 97/17</p> <p>selling [31] 10/11 10/11 11/4 12/6 19/4 23/21 24/21 30/8 58/2 62/6 70/6 74/12 102/1 102/3 106/24 108/17 108/19 109/1 109/7 109/8 111/19 112/2 126/20 140/3 144/10 149/5 149/7 150/10 150/20 151/6 153/4</p> <p>sense [6] 83/14 101/11 101/20 103/14 140/19 141/25</p> <p>sentence [1] 116/25</p> <p>separate [4] 5/19 59/15 59/23 144/5</p> <p>separated [2] 4/4 65/6</p> <p>separately [1] 138/22</p> <p>serious [1] 144/18</p> <p>serve [8] 63/11 63/23 64/1 64/8 65/18 65/25 68/12 97/7</p> <p>served [1] 30/9</p> <p>serves [1] 71/12</p> <p>Services [3] 4/24 5/5 5/11</p> <p>session [1] 79/25</p> <p>set [22] 8/20 9/11 11/21 23/17 25/8 32/12 37/1 40/12 40/24 43/9 44/18 47/1 48/25 81/1 82/15 121/8 142/2 142/16 152/6 160/24 161/11 161/15</p> <p>sets [2] 67/12 91/17</p> <p>Setting [1] 83/25</p> <p>setup [1] 4/4</p> <p>seven [2] 10/14 24/18</p> <p>several [12] 9/12 16/1 25/17 28/17 37/13 48/12 61/22 104/23 107/14 146/1 146/3 154/3</p> <p>shall [1] 75/23</p> <p>shallow [1] 49/16</p> <p>shape [1] 114/7</p> <p>she [15] 3/8 3/11 3/14 3/16 4/2 17/9 67/11 81/3 92/20 92/21 92/23 92/24 92/25 95/9 136/21</p> <p>shelves [5] 24/16 41/8 51/10 77/25 137/9</p> <p>shield [4] 29/6 37/4 48/8 93/17</p>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>S</p> <p>shielded [1] 136/13</p> <p>shields [2] 74/24 151/15</p> <p>ship [4] 89/3 89/4 89/9 90/3</p> <p>shipment [9] 88/25 89/1 89/18 110/14 110/16 110/16 110/20 111/3 111/6</p> <p>shipments [3] 89/8 89/25 111/11</p> <p>shipped [1] 116/7</p> <p>shipping [6] 116/3 116/20 116/23 117/14 117/18 117/23</p> <p>ships [1] 95/3</p> <p>Shop [1] 66/20</p> <p>short [2] 86/20 119/1</p> <p>shorten [1] 36/5</p> <p>shorten an [1] 36/5</p> <p>shortened [3] 36/8 36/13 36/20</p> <p>shortened our [1] 36/13</p> <p>shortening [2] 41/10 41/20</p> <p>shorter [6] 19/9 19/16 39/22 39/24 40/20 41/3</p> <p>should [53] 11/3 12/1 12/2 12/3 12/5 16/11 16/19 18/10 21/24 25/1 29/16 39/24 40/24 43/17 44/7 45/18 47/4 49/25 53/9 61/23 68/24 69/11 86/3 93/2 98/2 100/22 103/17 108/15 111/2 111/6 111/7 111/10 113/8 114/17 116/7 118/8 126/15 126/16 127/25 128/15 128/24 133/8 133/14 133/17 133/18 133/21 134/13 136/16 137/24 137/25 158/13 158/24 159/8</p> <p>shoulder [1] 139/19</p> <p>shouldn't [3] 86/18 86/20 97/21</p> <p>show [4] 25/23 31/22 105/10 110/3</p> <p>shows [3] 78/3 114/15 118/20</p> <p>side [7] 26/1 28/1 113/25 114/1 130/11 135/3 135/8</p> <p>sides [3] 81/17 146/2 153/9</p> <p>sidestep [1] 127/19</p> <p>signals [1] 71/9</p> <p>Signature [1] 162/6</p> <p>significant [7] 24/11 24/14 104/4 114/19 123/8 135/19 152/9</p> <p>significantly [1] 119/13</p> <p>similar [3] 16/12 22/8 106/12</p> <p>similarly [5] 72/14 93/6 111/5 136/18 140/2</p> <p>simple [3] 13/15 18/16 31/10</p> <p>simplistic [1] 130/8</p> <p>simply [23] 9/23 10/11 15/20 19/3 28/13 29/6 41/10 47/8 47/12 58/2 61/13 68/12 68/15 96/21 103/19 129/12 130/11 131/19 132/5 135/14 135/21 136/11 160/18</p> <p>simultaneously [4] 25/24 33/3 93/22 112/13</p> <p>since [9] 30/7 82/18 82/19</p>	<p>98/7 105/22 114/18 122/8 144/1 152/2</p> <p>single [9] 11/15 13/16 31/16 75/23 130/18 140/15 140/25 142/4 149/23</p> <p>sit [1] 103/15</p> <p>site [1] 103/25</p> <p>sits [1] 41/8</p> <p>sitting [1] 140/25</p> <p>situation [7] 15/17 24/17 94/1 113/15 113/16 152/2 157/25</p> <p>six [2] 2/9 70/25</p> <p>Sixth [4] 17/20 49/2 50/3 152/3</p> <p>size [1] 133/22</p> <p>skepticism [1] 56/19</p> <p>skipping [1] 120/14</p> <p>slap [1] 44/10</p> <p>slightly [2] 85/16 92/10</p> <p>sliver [2] 132/24 133/19</p> <p>slivers [2] 133/10 133/13</p> <p>smaller [1] 49/15</p> <p>Smith [2] 22/22 85/23</p> <p>smoked [1] 24/8</p> <p>snippets [1] 142/9</p> <p>so [195]</p> <p>so-called [3] 35/10 83/19 97/12</p> <p>society [1] 96/23</p> <p>sold [8] 12/6 22/14 24/6 40/5 73/4 73/4 92/20 122/14</p> <p>sole [5] 5/1 9/22 44/23 83/22 98/24</p> <p>solely [3] 18/9 33/23 33/24</p> <p>some [46] 5/22 13/13 26/24 32/11 36/24 45/14 48/17 51/4 51/5 51/6 51/20 52/1 55/21 56/18 66/8 77/14 87/4 93/23 94/13 97/19 99/10 101/15 102/15 115/6 122/2 122/11 132/3 132/25 133/13 133/16 133/19 134/24 141/17 142/9 142/24 144/4 144/6 147/13 148/19 150/1 153/24 154/24 158/13 158/22 160/13 161/14</p> <p>Some Courts [1] 144/6</p> <p>somebody [1] 15/22</p> <p>somehow [6] 12/1 13/4 21/24 76/2 150/16 155/18</p> <p>someone [1] 75/23</p> <p>something [29] 4/2 11/7 30/24 38/1 38/7 43/19 46/13 50/17 59/11 65/13 66/2 83/3 98/7 106/17 107/15 109/2 109/16 109/18 110/4 115/23 133/6 136/20 144/11 145/23 151/2 153/7 156/2 157/2 160/7</p> <p>sorry [9] 10/3 38/3 38/18 40/1 66/17 110/7 125/24 150/15 159/15</p> <p>sort [10] 19/7 54/19 56/13 61/19 93/19 102/15 108/4 113/6 135/2 139/10</p> <p>sorts [1] 100/16</p> <p>sought [1] 89/22</p> <p>sound [2] 95/8 156/12</p>	<p>sounding [1] 147/21</p> <p>sounds [2] 82/5 98/3</p> <p>source [4] 126/10 130/21 130/22 130/24</p> <p>South [3] 2/5 2/13 77/23</p> <p>SOUTHERN [6] 1/1 14/14 14/16 17/21 18/22 85/23</p> <p>sovereign [1] 141/21</p> <p>sovereigns [1] 97/22</p> <p>sovereigns' [1] 37/1</p> <p>space [2] 142/24 143/9</p> <p>speak [2] 37/11 38/16</p> <p>speaking [6] 4/22 60/14 81/1 81/2 81/7 125/8</p> <p>special [3] 36/9 42/5 91/15</p> <p>specific [18] 15/6 18/25 58/12 58/15 59/7 74/10 78/13 94/19 105/7 112/16 116/22 117/7 117/8 124/8 149/25 154/6 154/7 158/11</p> <p>specifically [9] 50/16 67/14 76/7 88/11 101/19 117/23 143/14 146/18 159/12</p> <p>specificity [1] 119/20</p> <p>specified [2] 144/17 158/14</p> <p>speculate [1] 56/25</p> <p>speculation [1] 117/9</p> <p>speculative [3] 55/3 55/7 55/10</p> <p>speculative mouse [1] 55/7</p> <p>spend [4] 10/20 14/1 17/9 103/11</p> <p>spent [2] 8/8 82/12</p> <p>spoke [1] 104/5</p> <p>spread [1] 71/12</p> <p>square [2] 112/20 139/11</p> <p>squarely [9] 18/10 34/8 62/5 76/11 102/2 102/24 139/8 151/25 156/22</p> <p>stability [2] 40/24 79/13</p> <p>staff [1] 96/17</p> <p>stage [6] 21/22 23/17 39/4 45/9 62/22 115/20</p> <p>staggering [1] 129/25</p> <p>stake [1] 86/19</p> <p>stand [4] 31/16 48/16 86/5 92/9</p> <p>standard [8] 36/15 40/15 77/16 108/1 117/24 118/1 118/22 127/24</p> <p>standards [3] 3/17 3/18 130/16</p> <p>standing [2] 144/9 160/15</p> <p>stands [1] 109/5</p> <p>stare [1] 29/22</p> <p>start [13] 23/13 35/9 42/17 54/9 55/20 91/11 98/16 108/17 108/18 129/16 130/11 143/23 152/21</p> <p>starting [5] 13/9 26/8 32/21 55/7 92/18</p> <p>starts [2] 19/15 47/6</p> <p>state [252]</p> <p>state and [1] 141/13</p> <p>state design [1] 27/20</p> <p>state law [1] 21/5</p> <p>state lets [1] 149/23</p> <p>state's [5] 33/24 34/18 65/5</p>
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>S</p> <p>state's... [2] 91/18 158/23</p> <p>state-law [1] 104/19</p> <p>stated [15] 18/8 28/9 50/5 52/4 53/3 53/6 71/7 113/5 131/25 132/4 136/18 137/12 138/12 145/17 152/12</p> <p>statement [14] 75/6 89/1 89/2 89/12 89/14 89/14 89/19 89/21 90/1 90/19 90/21 103/8 104/2 111/25</p> <p>statements [12] 63/2 73/11 73/11 73/16 88/23 99/17 103/7 111/12 118/23 119/1 119/4 126/17</p> <p>states [58] 1/1 1/10 5/5 5/20 24/4 24/6 29/19 29/21 32/4 32/6 32/11 32/14 37/15 47/11 49/7 51/20 52/9 55/22 56/2 57/2 76/13 89/8 95/19 97/11 97/19 97/22 97/24 98/11 104/11 111/23 116/13 128/1 128/23 129/18 140/18 141/10 141/17 141/19 141/21 144/19 147/20 148/6 148/10 149/4 149/13 149/20 151/5 153/24 154/3 158/14 158/17 159/2 159/6 159/24 160/1 160/5 160/13 160/15</p> <p>states' [1] 24/21</p> <p>stating [1] 64/8</p> <p>status [1] 161/15</p> <p>statute [41] 14/23 14/23 14/25 20/25 21/13 28/25 30/12 65/1 75/17 76/18 76/20 88/8 88/12 90/9 90/12 99/1 99/5 100/19 103/22 104/10 104/11 108/22 111/16 111/17 126/9 126/11 128/4 130/23 131/1 135/4 135/7 135/15 136/1 141/5 146/4 146/25 147/12 148/17 151/18 153/16 153/23</p> <p>statute defines [1] 65/1</p> <p>statute's [3] 28/5 99/11 103/24</p> <p>statutes [6] 15/10 16/8 97/13 97/25 147/22 148/18</p> <p>statutory [14] 15/6 34/6 73/12 94/11 98/20 98/22 98/24 99/24 100/23 105/16 109/7 135/9 136/16 140/4</p> <p>stay [3] 37/8 49/15 80/7</p> <p>stayed [1] 57/1</p> <p>staying [1] 120/3</p> <p>Stengel [4] 32/22 33/7 33/15 56/10</p> <p>step [8] 8/24 11/10 43/16 54/7 70/15 79/8 79/8 126/23</p> <p>sticking [1] 121/17</p> <p>still [19] 27/6 34/4 42/11 53/13 53/15 55/12 66/1 68/25 71/9 92/7 106/25 117/6 122/3 122/4 133/18 137/15 142/24 159/21 160/16</p> <p>stipes [11] 2/17 3/8 3/8 3/10 3/22 4/1 4/9 40/2 110/7</p>	<p>156/9 162/5</p> <p>stipulate [4] 100/8 100/14 120/4 121/25</p> <p>stomach [1] 45/14</p> <p>stop [23] 4/2 19/3 24/21 30/8 62/6 70/6 74/12 102/1 102/3 108/25 109/6 109/8 111/19 112/2 126/20 140/3 149/5 149/7 150/10 150/20 150/23 151/6 153/4</p> <p>stopped [1] 12/6</p> <p>stopping [1] 106/23</p> <p>stops [1] 84/20</p> <p>storage [45] 20/1 20/1 20/4 44/8 46/2 46/5 46/8 46/15 47/8 48/24 50/16 51/9 70/21 77/13 78/6 79/10 112/8 112/9 112/10 113/7 113/8 113/12 113/18 114/10 114/19 115/5 115/10 115/22 116/3 116/8 116/11 116/14 116/20 116/23 117/14 117/18 117/23 117/25 118/14 118/18 119/15 120/17 131/15 133/1 133/2</p> <p>store [17] 41/8 47/12 47/15 47/17 49/5 112/7 112/13 112/17 112/17 113/11 114/4 114/5 115/9 115/10 121/12 122/16 123/11</p> <p>stored [8] 47/5 113/7 113/21 115/15 116/7 119/17 123/17 123/20</p> <p>storing [1] 123/19</p> <p>Strahorn [2] 50/2 72/15</p> <p>straightforward [4] 8/22 22/11 82/5 87/15</p> <p>strange [1] 27/14</p> <p>Street [5] 1/17 1/20 2/5 2/9 2/13</p> <p>strength [1] 40/13</p> <p>stretch [1] 116/24</p> <p>strict [27] 58/18 58/21 59/4 59/4 60/23 61/3 71/5 71/8 71/14 75/11 95/1 95/8 95/13 95/15 95/18 96/11 97/2 98/12 102/4 102/6 102/20 102/20 107/13 107/16 109/23 110/2 111/17</p> <p>Striker [1] 32/23</p> <p>stringent [4] 90/10 90/12 90/18 90/24</p> <p>strip [5] 133/9 133/23 133/24 134/13 134/14</p> <p>stripped [1] 131/20</p> <p>strong [2] 97/20 124/4</p> <p>student [1] 78/8</p> <p>studies [1] 119/7</p> <p>style [1] 33/15</p> <p>styled [1] 7/2</p> <p>styling [1] 26/17</p> <p>stylized [3] 27/3 59/3 93/19</p> <p>subdivision [1] 99/13</p> <p>subject [6] 12/15 23/2 29/4 35/18 71/2 72/19</p> <p>subjected [2] 75/17 77/17</p> <p>submission [1] 36/15</p> <p>submitted [2] 24/20 35/5</p> <p>subsection [5] 36/6 75/22</p>	<p>110/18 127/9 127/21</p> <p>subsections [5] 146/3 146/16 146/17 146/19 146/24</p> <p>subsequent [2] 90/2 150/1</p> <p>subsequently [1] 33/8</p> <p>substance [1] 26/21</p> <p>substantial [1] 13/19</p> <p>substantive [2] 81/1 93/15</p> <p>substantively [1] 26/11</p> <p>subsume [1] 60/13</p> <p>subsumed [3] 58/25 59/18 60/3</p> <p>succeed [3] 25/4 25/5 56/19</p> <p>successfully [1] 94/13</p> <p>such [26] 10/19 16/15 17/24 19/8 25/7 27/11 27/12 32/4 32/8 36/22 40/20 60/10 71/20 73/13 95/11 96/22 99/19 99/20 113/8 118/11 126/21 127/14 128/8 128/17 148/21 160/19</p> <p>sucks [1] 131/19</p> <p>sue [2] 87/12 96/12</p> <p>suffered [1] 76/17</p> <p>sufficient [4] 13/18 118/5 133/6 149/23</p> <p>suggest [2] 157/9 157/10</p> <p>suggest that [1] 157/9</p> <p>suggested [1] 151/21</p> <p>suggesting [3] 86/2 150/16 156/1</p> <p>suggestion [3] 5/17 116/1 116/18</p> <p>Suite [3] 1/13 1/23 2/10</p> <p>Sulindac [1] 30/5</p> <p>summary [6] 20/15 63/4 119/6 119/24 120/1 139/1</p> <p>summer [2] 77/21 77/24</p> <p>superiority [1] 15/16</p> <p>superiority of [1] 15/16</p> <p>supplement [1] 35/17</p> <p>supplemental [1] 36/1</p> <p>supplementing [1] 35/21</p> <p>supplements [1] 35/19</p> <p>supply [20] 67/6 68/1 68/14 69/14 82/24 83/6 84/24 87/3 87/7 98/15 103/21 110/9 110/13 110/23 110/25 122/6 122/7 122/13 122/19 122/23</p> <p>support [7] 14/18 78/7 113/24 117/1 117/2 133/19 138/4</p> <p>supporting [1] 122/10</p> <p>supports [1] 116/18</p> <p>suppose [2] 27/4 112/10</p> <p>suppose the [1] 112/10</p> <p>supposed [1] 40/25</p> <p>supposedly [1] 102/22</p> <p>supremacy [10] 10/23 11/12 14/20 15/14 15/15 16/11 18/14 33/17 76/2 137/24</p> <p>supreme [43] 8/18 8/21 10/2 10/3 17/18 25/13 25/21 26/5 26/15 27/15 27/23 28/24 29/9 29/13 29/18 29/20 29/25 33/7 48/14 50/10 52/4 55/5 56/7 69/4 70/8 71/5 71/16 74/14 75/10 95/13 97/4 98/21 105/7</p>
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

S supreme... [10] 128/16 135/16 142/13 143/11 149/2 149/17 151/2 152/5 152/17 153/8 sure [17] 3/18 37/10 38/5 66/2 81/11 81/23 96/17 98/2 99/8 107/11 115/15 129/7 137/17 146/14 147/6 156/11 156/12 surmise [1] 149/18 surmise that [1] 149/18 surprising [2] 26/14 148/6 surrounding [1] 136/19 survey [3] 148/16 149/16 158/21 survive [15] 13/25 18/12 26/11 31/8 31/23 50/10 77/8 133/18 142/10 142/11 142/14 142/15 142/22 149/14 158/20 survive so [1] 133/18 survived [1] 123/25 survives [1] 133/14 surviving [1] 134/3 suspect [7] 3/7 56/19 63/19 88/20 88/21 89/4 90/23 suspected [1] 89/17 swaths [1] 129/14 switch [1] 96/8 synonyms [1] 100/4 syrup [3] 11/16 20/3 20/3 system [7] 87/25 88/9 99/15 99/22 100/8 103/6 141/23 systems [4] 88/21 89/4 99/19 99/20	152/18 temperature [21] 49/8 49/9 50/17 77/21 78/13 112/24 113/22 114/3 116/8 116/20 117/21 117/22 117/24 118/1 119/18 120/1 120/19 121/17 123/18 123/19 123/21 temperature and [1] 120/19 temperatures [17] 47/9 70/21 112/9 112/14 112/18 115/15 116/8 117/3 117/18 117/19 118/15 119/5 119/9 121/13 121/14 122/15 122/16 term [2] 99/5 129/5 terms [9] 6/21 8/2 25/22 63/12 67/19 76/9 81/6 99/2 140/7 territories [1] 159/2 territory [1] 155/9 test [4] 18/25 19/3 57/25 88/11 tested [4] 78/4 117/15 117/20 118/2 testing [8] 18/18 40/24 51/2 77/12 78/2 114/15 115/4 116/13 Teva [2] 14/16 22/22 Texas [1] 97/11 text [9] 88/8 90/8 98/23 98/24 99/1 135/9 135/15 136/1 140/19 textbook [1] 24/17 than [29] 5/20 16/14 39/12 39/17 51/14 59/22 73/16 79/16 85/11 90/10 90/12 90/13 90/18 90/21 90/24 102/1 102/8 114/14 119/7 120/19 120/20 121/8 121/13 126/17 132/7 138/14 153/18 156/2 157/2 thank [67] 4/18 6/13 6/15 6/17 6/21 15/24 15/25 20/17 20/19 20/21 23/2 23/3 37/6 37/8 37/21 44/15 50/12 50/13 51/18 55/14 55/15 55/18 58/8 60/17 61/17 65/7 66/4 66/5 67/22 67/24 73/19 73/21 73/24 78/25 79/23 79/24 80/11 87/5 87/8 91/4 91/8 100/24 100/25 105/18 105/20 110/8 121/5 122/5 122/20 124/18 125/19 125/24 129/2 129/3 134/20 134/22 143/18 143/19 145/13 145/14 152/22 157/7 160/22 161/1 161/4 161/5 161/19 Thanks [2] 48/20 54/9 that [1272] that express [1] 49/24 that FDA [1] 101/19 that has [1] 95/18 that is [1] 154/21 that stop [1] 150/10 that successfully [1] 94/13 that we [1] 30/19 that's [14] 14/15 22/23 25/15 28/7 28/9 34/11 46/20 63/10 78/12 84/9 107/20	110/17 112/22 122/2 the absolute [1] 102/4 the announcement [1] 103/21 the design [2] 84/16 134/9 the Drug [1] 90/9 the expiration [2] 35/15 41/10 the express [1] 129/16 the facilities [1] 51/9 the FDA's [1] 115/18 the Federal [2] 21/16 131/16 the generic [1] 16/3 the high [1] 77/14 the lack [1] 113/23 the medical [1] 131/10 The penultimate [1] 33/20 the questions [1] 50/5 the reply [1] 147/14 the rule [1] 45/17 the Sixth [1] 50/3 the state [1] 22/18 their [113] 10/25 13/3 13/24 14/7 14/8 15/19 16/18 18/8 19/20 19/21 21/16 21/23 22/4 22/5 22/24 23/1 31/1 31/2 32/15 32/18 33/1 34/12 35/2 35/5 36/8 36/11 36/25 42/4 42/18 42/20 42/21 42/22 44/11 45/4 45/19 45/23 46/12 46/23 49/5 49/19 50/16 51/20 52/3 56/23 57/1 63/19 65/14 66/22 67/16 70/14 72/5 72/10 73/2 73/3 73/6 74/22 76/13 76/24 76/24 77/10 78/5 79/4 81/15 85/5 85/6 85/21 86/9 87/23 87/25 93/10 95/22 96/19 97/23 102/10 102/24 108/2 111/25 114/2 117/10 121/21 121/23 123/9 123/11 125/3 126/19 126/24 126/25 127/17 127/20 128/9 128/23 130/1 130/3 130/3 130/6 130/9 133/6 133/19 136/7 136/10 137/23 137/23 139/1 139/11 139/24 140/22 141/23 145/9 146/2 148/4 148/7 151/15 157/20 their claims [1] 126/25 them [42] 3/20 3/21 11/11 12/21 26/24 28/18 31/19 37/5 45/19 48/3 55/23 57/3 63/19 68/16 68/17 71/20 74/24 74/24 82/10 89/25 92/6 94/6 94/23 97/19 105/24 108/17 108/18 109/6 109/8 121/11 121/16 123/7 123/9 123/10 123/16 136/15 138/21 139/9 139/16 140/23 140/24 151/15 them and [1] 139/9 them that [1] 94/23 theme [1] 141/20 themselves [3] 80/17 97/10 97/17 then [37] 7/10 9/8 16/23 17/21 23/14 25/5 25/18 36/15 39/2 44/10 47/1 54/18 63/7 66/9 67/17 67/23 70/4 71/14 75/25 87/3 99/16 99/18
T tablet [1] 11/16 tactical [1] 63/20 take [22] 3/5 4/10 6/18 7/17 8/4 8/5 8/9 8/15 20/16 23/17 30/1 34/10 39/3 43/16 50/18 55/4 61/23 92/13 106/25 119/11 125/12 161/16 taken [4] 24/2 43/17 54/20 80/12 takes [1] 6/14 taking [4] 7/15 9/7 119/24 155/1 talk [3] 74/8 97/13 115/3 talked [1] 146/1 talking [10] 32/25 43/7 91/25 92/16 92/17 100/20 134/24 138/7 143/14 151/12 talks [2] 114/9 153/1 tap [1] 139/19 task [1] 161/13 teaching [5] 26/19 36/21 41/22 95/4 148/2 teachings [1] 59/1 team [1] 96/16 technical [2] 137/14 137/15 technically [3] 109/5 137/10 154/13 teeth [1] 122/2 tell [2] 81/20 137/8 telling [3] 61/13 108/25		

T	158/13 160/5 160/12 160/13 160/18	Thornburg [2] 1/22 2/5
then... [15] 105/14 122/21 125/13 127/2 132/2 133/10 133/11 133/24 134/1 134/25 135/6 136/5 146/14 153/7 160/13	there's [1] 31/19	those [77] 3/17 3/18 16/3 21/21 22/20 23/14 27/11 29/4 30/21 34/15 41/14 41/21 42/7 42/11 45/15 47/18 48/2 48/18 48/21 53/17 53/18 53/20 53/25 57/23 58/2 58/4 58/25 59/6 59/7 59/18 60/21 61/5 61/8 63/25 70/8 71/22 71/25 74/16 76/3 77/22 78/14 80/10 84/8 85/4 91/17 93/4 93/24 94/15 95/10 95/22 97/18 97/23 97/25 100/16 114/11 121/13 122/15 123/24 124/10 128/14 133/5 133/13 136/8 136/14 139/24 140/1 140/22 140/24 140/24 142/20 143/6 144/21 148/13 148/19 155/7 155/7 159/17
theoretically [1] 79/21	thereby [1] 83/6	those causes [1] 76/3
theories [37] 11/24 12/23 12/25 13/3 13/6 13/10 13/18 14/2 19/8 50/9 57/16 58/6 68/15 93/4 93/23 93/24 94/6 94/8 94/15 94/17 94/24 94/24 95/16 122/4 126/22 126/25 133/15 133/18 133/23 134/13 134/14 137/18 137/22 137/25 138/1 138/3 155/7	thereof [1] 151/21	though [15] 24/19 27/11 45/8 56/3 56/20 64/5 65/22 96/24 96/25 98/1 107/11 108/22 137/22 140/23 154/17
theories in [1] 134/13	thereon [1] 28/9	thought [1] 60/4
theory [65] 5/6 6/7 13/24 14/10 14/15 17/14 18/9 23/14 23/16 24/18 25/3 25/4 25/5 27/18 30/21 31/1 31/1 31/2 32/1 32/5 33/23 34/8 34/20 36/17 44/23 45/1 45/19 61/9 62/6 74/11 77/6 86/17 92/3 92/23 92/24 93/1 93/7 93/8 93/13 93/14 93/17 102/3 102/20 102/21 102/24 113/24 118/4 129/12 135/9 137/19 138/4 138/5 138/12 138/13 138/15 138/18 140/2 149/23 151/6 151/22 151/25 152/5 152/8 158/16 159/8	Thereupon [2] 80/12 161/21	thousand [2] 75/18 76/15
there [159] 3/14 3/22 4/19 7/18 7/19 8/7 9/18 10/15 10/18 12/12 12/12 12/23 14/2 14/4 15/22 16/1 16/15 16/24 17/9 17/16 19/25 20/22 25/17 25/18 25/19 26/8 27/7 29/6 30/2 30/12 30/13 33/16 35/13 35/14 35/24 36/10 37/13 40/15 41/4 41/5 41/5 42/19 43/20 47/1 47/18 47/22 48/16 51/3 51/4 53/11 53/12 54/13 55/22 56/2 56/20 60/12 60/25 61/24 63/1 63/24 65/13 65/22 66/2 70/1 70/5 71/7 72/25 73/11 73/11 74/22 75/4 75/5 75/5 76/18 78/18 78/23 79/7 82/17 93/3 93/17 95/11 96/5 96/12 97/15 98/10 99/16 100/18 102/8 102/19 103/12 103/19 104/4 108/2 108/4 108/24 109/10 110/10 111/22 113/2 113/19 113/25 114/10 115/21 117/18 119/12 121/9 121/18 123/3 125/1 125/17 129/17 132/5 132/6 132/10 133/1 133/3 133/3 134/1 136/19 137/14 137/22 138/4 138/7 138/17 138/20 139/25 140/6 140/11 141/17 142/24 143/4 143/16 144/1 144/4 144/5 145/12 147/15 148/19 148/20 149/4 149/6 150/17 152/8 154/18 154/24 155/3 156/3 156/23 156/23 157/9 157/25 158/1 158/3 158/13	Thermo [1] 5/2	threadbare [1] 118/24
	Thesaurus [1] 100/4	three [19] 8/24 11/10 11/13 11/24 12/5 17/16 26/8 40/5 40/7 40/10 40/14 51/22 52/19 124/24 125/12 125/13 125/15 125/17 127/13
	these [53] 5/25 11/1 12/25 13/3 13/6 13/10 13/12 14/1 15/19 19/5 27/17 33/17 51/8 51/16 52/19 55/21 55/24 58/5 59/7 59/22 61/6 63/2 63/6 68/19 73/8 76/14 77/15 78/19 78/22 84/19 86/14 95/7 111/12 114/14 114/20 121/20 126/13 130/20 130/25 133/9 133/11 133/18 133/20 134/2 136/2 137/8 140/17 140/17 141/20 142/3 142/25 146/22 160/24	three corollaries [1] 26/8
	they [277]	three-month [3] 40/5 40/7 40/14
	they are [1] 63/21	three-step [2] 8/24 11/10
	they certainly [1] 139/6	through [38] 1/9 9/14 12/10 12/20 14/1 14/9 21/4 34/22 35/17 35/19 36/4 44/17 45/12 50/23 73/14 73/17 76/23 78/3 82/2 83/25 87/24 88/9 99/15 99/22 100/7 103/6 108/23 120/23 122/7 122/12 122/19 133/9 137/1 137/11 140/4 143/12 143/13 158/22
	they turn [1] 117/11	throughout [5] 82/11 119/2 127/16 141/20 149/4
	thin [1] 86/21	throw [1] 93/11
	thing [12] 16/15 29/3 29/11 31/12 35/1 36/12 77/23 90/1 95/11 129/17 131/23 142/1	thrown [2] 17/2 86/3
	things [21] 6/22 23/25 36/24 42/1 50/22 51/22 52/20 53/17 53/18 53/20 53/20 54/16 65/2 94/12 94/13 94/18 107/2 123/4 129/10 136/23 159/4	thus [5] 5/3 20/13 72/11 90/24 128/24
	things where [1] 53/17	thy [1] 78/4
	think [101] 4/11 6/5 8/4 9/21 9/24 10/20 11/10 13/21 18/11 20/15 29/12 34/20 38/12 41/4 41/5 43/6 47/16 49/6 50/24 51/7 51/16 53/1 56/10 56/18 57/5 59/15 59/24 60/19 61/6 61/8 61/20 62/5 62/6 63/4 65/9 65/10 65/24 67/3 71/25 72/24 74/2 74/4 77/9 81/23 81/24 82/20 83/1 83/20 86/8 91/10 92/11 95/3 95/7 97/8 99/3 99/9 106/24 107/18 107/20 107/21 112/22 113/23 114/3 114/11 114/13 115/12 115/19 118/20 118/22 119/14 120/5 121/11 122/23 123/7 129/17 131/21 133/7 133/15 135/2 135/24 136/21 138/8 144/14 146/12 147/12 147/24 149/6 149/10 149/23 151/12 152/18 153/11 154/13 156/1 156/7 157/7 158/3 158/20 158/21 159/21 160/10	ties [1] 138/9
	thinks [3] 59/23 96/15 96/19	time [45] 6/21 7/11 7/19 7/20 8/6 8/7 10/14 10/20 13/10 13/10 14/1 17/9 17/11 19/21 19/21 23/21 24/14 28/22 37/7 38/21 45/9 51/3 67/3 67/10 73/19 77/21 81/8 81/12 81/15 81/17 82/3 82/4 82/13 86/13 91/1 91/5 103/2 103/18 123/9 125/5 125/12 125/18 125/19 144/1 144/1
	third [9] 9/6 14/5 32/7 33/9 52/13 69/14 134/1 134/3 146/8	time creating [1] 77/21
	this [252]	timely [1] 161/9
	this question [1] 120/2	times [8] 9/12 26/6 72/25 98/22 107/14 129/6 134/15
	THOMAS [3] 1/19 38/8 39/5	

T times... [1] 155/18 timing [1] 81/6 title [4] 59/18 77/2 147/25 148/4 titled [3] 38/24 59/13 95/12 to a [1] 100/12 to address [1] 74/6 to apply [1] 105/11 to avoid [1] 43/10 to capture [1] 88/19 to do [1] 66/1 to impose [1] 110/24 to pull [1] 151/18 to such [1] 99/19 to the [1] 32/9 tobacco [1] 49/21 today [29] 4/11 6/19 11/14 24/6 24/13 25/21 29/15 31/16 52/1 62/17 66/21 78/1 82/13 84/2 84/8 108/6 109/11 109/16 110/11 116/6 124/22 129/6 131/24 134/11 134/15 145/9 146/2 146/5 153/22 today's [1] 92/17 together [3] 3/16 6/23 74/2 told [2] 24/2 30/8 tomorrow [2] 34/1 34/2 too [7] 18/16 21/6 22/10 41/9 43/14 72/7 152/21 took [5] 75/23 76/25 96/4 100/11 119/17 toothless [1] 87/1 top [1] 43/2 topic [5] 41/15 46/1 91/19 109/10 118/13 tort [1] 34/12 torts [3] 27/11 160/3 160/4 total [1] 24/1 totality [1] 41/14 touch [2] 74/5 157/5 touched [1] 53/2 touching [1] 107/18 tougher [1] 41/5 towards [2] 16/7 82/21 trace [4] 100/1 100/2 100/5 123/14 tracing [25] 87/24 88/9 88/13 88/22 99/4 99/4 99/5 99/14 99/21 99/23 100/20 100/20 103/5 111/12 122/7 122/9 122/12 122/19 122/24 123/1 123/3 123/5 123/9 123/20 123/21 track [3] 47/2 100/2 100/5 tracked [1] 100/7 tracking [1] 55/7 trading [1] 90/2 traditional [1] 98/12 trail [1] 100/2 transaction [13] 88/14 88/23 89/1 89/2 89/12 89/13 89/19 89/20 90/18 90/21 99/18 103/7 103/7 transcribing [1] 3/12 transcript [3] 136/22 156/8 162/1	transition [1] 34/19 transport [6] 46/15 114/10 114/20 115/22 119/15 120/18 transportation [6] 46/2 46/5 51/9 77/13 78/6 131/15 trap [1] 57/2 Traynor [1] 96/22 Treating [1] 141/21 tree [1] 4/19 trenchant [1] 56/11 trial [1] 50/4 tried [4] 35/4 57/14 61/20 131/2 tries [1] 153/7 truck [2] 77/20 123/7 truck outside [1] 123/7 true [14] 21/5 21/15 57/1 65/16 76/19 94/7 101/12 114/12 119/6 131/5 131/9 131/21 135/18 149/3 try [10] 33/22 53/7 79/19 93/10 109/22 110/2 121/24 129/25 130/24 131/10 trying [7] 29/10 34/5 57/16 84/23 132/17 157/9 157/10 Tsavaris [2] 52/17 57/20 TTP [1] 22/7 turn [21] 6/19 7/8 7/9 28/5 37/9 54/5 58/7 63/19 66/7 71/24 80/9 87/2 89/23 95/1 102/25 117/11 134/25 138/19 140/10 141/5 141/7 turning [6] 46/21 55/1 62/10 65/23 69/23 99/8 turns [2] 84/9 119/23 twelve [1] 80/1 twist [2] 74/9 74/21 two [37] 5/5 8/6 8/18 12/2 17/2 18/19 19/13 20/22 23/25 25/22 42/25 43/2 48/18 49/10 52/2 53/20 61/2 61/8 67/2 70/8 80/3 82/13 82/21 84/3 85/6 87/18 103/12 106/2 109/22 110/6 112/14 123/21 142/17 159/2 160/25 161/2 161/4 two-year [1] 19/13 Twombly [2] 118/4 118/22 Twombly which [1] 118/22 tying [1] 73/6 type [6] 43/23 143/4 152/7 154/7 158/11 160/3 types [1] 148/14 typically [1] 109/1	unanimous [1] 32/22 unbroken [1] 32/21 unclear [2] 55/10 147/5 under [129] 8/13 8/14 9/1 9/4 9/10 11/20 13/19 18/11 20/2 20/11 20/13 21/7 21/16 22/11 22/15 22/17 22/19 27/24 28/4 30/11 30/12 31/23 32/4 32/11 32/16 33/16 33/17 33/24 34/4 34/18 35/8 36/5 39/20 40/11 40/15 42/1 42/11 43/3 43/18 43/22 45/1 46/12 47/18 48/7 48/10 49/1 52/15 52/24 53/21 54/17 55/12 57/2 57/15 58/13 58/17 58/21 59/19 59/24 62/13 65/5 65/19 69/4 70/2 70/24 71/23 72/3 72/12 73/13 74/13 74/18 74/20 74/23 75/2 75/17 75/22 87/7 87/14 87/17 88/4 90/11 91/24 92/21 93/20 94/8 94/12 94/19 95/11 95/12 95/15 95/17 96/11 98/10 102/20 105/6 107/16 111/16 112/15 113/2 117/17 118/4 119/16 121/23 122/4 127/24 127/25 128/16 130/20 135/1 137/24 138/15 138/15 139/12 139/23 139/23 141/12 142/19 142/19 144/24 145/11 149/2 149/10 151/4 153/17 153/19 153/24 154/8 157/14 158/16 159/7 under Rule [1] 121/23 under the [1] 55/12 underlying [1] 69/19 undermine [1] 94/5 understand [7] 4/13 51/22 80/18 103/4 121/7 125/1 147/7 understanding [1] 118/16 understands [1] 52/19 understate [1] 29/13 understatement [1] 24/5 Understood [1] 147/8 undertake [1] 40/25 undertaken [3] 114/20 149/12 159/23 undisputed [2] 20/24 22/14 unfortunately [3] 84/22 86/4 96/9 uniform [6] 12/16 78/3 141/2 141/10 141/19 158/24 uniform in [1] 141/10 uniformity [1] 12/11 uniformly [4] 11/11 13/6 109/3 147/24 unilateral [1] 79/13 unilaterally [8] 43/13 43/19 43/20 44/11 58/12 70/3 70/14 128/20 unintelligible [1] 3/23 unique [2] 68/1 113/16 uniquely [1] 68/14 UNITED [7] 1/1 1/10 24/4 24/6 29/19 29/21 111/23 unlawful [2] 108/17 108/18 unless [3] 88/25 89/8 102/10 Unlike [2] 24/23 107/25
	U U.S [5] 14/12 52/7 71/13 103/17 103/25 U.S. [1] 52/16 U.S.C [14] 15/3 28/7 28/12 62/13 64/12 74/20 75/15 76/21 99/11 110/17 111/1 146/4 146/11 153/16 ubiquitous [1] 24/4 ultimate [6] 18/24 32/9 46/17 54/12 54/13 55/11 ultimately [3] 5/11 56/4 159/19	

U unlikely [1] 71/18 unsafe [6] 19/1 72/14 126/8 126/15 131/19 144/10 unstable [1] 11/18 untested [1] 86/17 until [4] 67/15 105/23 117/10 147/14 untouched [1] 94/25 untrue [1] 131/20 unusual [1] 148/5 up [33] 3/5 4/10 7/11 24/1 25/9 30/1 31/17 32/13 37/12 54/6 54/7 55/25 61/14 74/17 80/20 81/6 81/20 95/10 107/2 109/10 115/6 117/11 124/21 124/23 125/5 125/11 125/15 134/3 135/8 137/17 147/5 156/10 161/16 up and [1] 95/10 up by [1] 25/9 update [4] 32/7 33/9 56/3 60/20 updating [1] 61/21 upend [1] 86/22 upon [8] 3/13 16/4 16/18 18/9 24/2 48/12 114/25 159/10 urging [1] 14/3 us [25] 3/24 4/5 24/24 26/17 29/10 29/12 30/1 30/8 41/22 64/2 64/6 65/12 94/16 94/18 95/24 101/20 103/14 121/2 121/2 123/16 135/22 138/7 138/18 150/14 158/23 use [17] 26/9 42/6 42/20 47/16 53/10 66/25 67/3 74/1 82/3 82/4 95/5 126/24 129/25 145/7 148/3 160/11 160/15 used [5] 26/14 28/8 49/25 91/4 151/20 useful [2] 91/10 92/12 using [2] 26/18 30/17 usually [3] 11/1 13/12 93/9	version [2] 39/13 39/17 versus [22] 8/3 8/19 11/6 14/15 18/20 18/21 25/18 32/5 36/7 52/15 52/17 55/24 60/21 95/1 102/4 102/19 103/17 105/9 109/20 139/8 139/20 157/22 vertical [1] 29/22 very [35] 3/24 8/19 8/21 9/10 11/22 16/9 16/16 16/20 18/8 22/4 23/2 23/3 42/22 43/2 43/11 43/12 54/2 55/2 56/10 74/11 76/20 79/2 79/12 79/24 89/18 100/17 102/13 120/19 120/20 144/14 152/18 152/22 159/13 159/25 161/19 vested [1] 103/20 VI [1] 25/15 viable [7] 18/5 79/20 79/21 85/15 126/23 128/21 138/15 video [3] 7/9 37/10 80/9 videos [1] 66/7 view [7] 16/4 18/13 59/18 61/19 87/25 130/8 143/3 viewed [1] 16/19 violate [1] 116/23 violated [7] 102/1 116/2 117/14 121/18 126/11 144/5 144/6 violates [1] 126/9 violating [2] 70/4 76/2 violation [9] 49/1 63/12 119/19 128/4 130/17 132/11 132/15 144/7 144/10 violations [1] 144/8 violators [1] 75/17 virtually [1] 27/25 volume [1] 54/6 voluntary [7] 108/8 108/16 108/23 109/6 132/1 137/1 137/7	32/7 33/15 34/24 51/21 52/14 52/21 54/13 55/1 58/16 59/4 59/5 59/7 59/13 59/16 59/17 60/6 60/12 60/21 60/23 60/23 61/3 61/4 63/22 70/9 72/12 128/24 134/10 138/24 139/13 155/5 156/4 156/16 warned [1] 12/1 warning [13] 8/12 10/4 32/9 42/10 52/24 53/15 55/5 55/7 59/10 59/17 72/10 125/16 155/15 warnings [21] 7/12 11/2 11/8 18/7 41/13 47/24 59/9 61/15 67/1 70/19 80/21 81/22 84/5 84/11 84/17 85/3 139/3 139/7 139/14 155/18 157/14 warns [1] 61/2 warrant [1] 82/17 warranted [1] 64/4 warranties [9] 64/1 64/17 64/21 64/23 65/11 69/21 72/18 72/19 72/21 warranty [40] 21/1 21/3 21/5 21/9 21/14 21/23 22/5 62/11 62/13 62/15 63/10 63/13 63/14 63/24 63/25 64/6 64/7 64/13 64/13 64/16 64/21 64/24 65/1 65/1 65/5 65/17 65/19 65/23 65/24 65/25 69/17 69/19 71/24 72/3 72/4 72/6 72/14 72/17 73/2 73/6 was [93] 4/21 5/9 6/9 10/13 10/14 14/13 17/6 17/22 23/19 23/23 24/4 24/12 29/7 36/6 38/15 40/23 41/17 50/17 55/2 56/13 56/15 59/3 63/24 64/5 69/24 70/2 71/15 76/25 79/5 80/12 81/7 81/11 88/1 89/15 89/17 91/19 95/2 95/13 96/6 97/4 100/12 101/18 101/21 103/11 105/22 107/17 107/18 108/2 108/15 109/15 109/19 109/24 110/4 112/1 113/5 113/6 114/10 114/19 115/19 117/5 119/25 122/24 126/17 128/17 133/3 133/3 136/12 137/9 137/10 137/21 138/13 142/6 143/11 144/4 144/5 144/17 145/18 146/11 147/4 151/1 151/13 151/13 151/22 152/24 152/24 153/2 156/8 157/8 158/5 158/9 159/17 160/10 161/21 Washington [1] 2/2 wasn't [2] 46/19 159/18 watching [1] 161/3 Watford [2] 56/13 57/5 Watford's [2] 56/9 56/18 way [20] 5/7 14/8 14/9 15/18 18/3 19/1 45/25 47/12 60/2 79/15 79/16 92/10 107/16 107/20 107/21 132/3 133/21 141/12 154/15 156/16 we [319] we pleaded [1] 121/20 we'll [2] 66/10 109/2 we're [2] 131/3 149/25
V vaccine [1] 102/14 vacuum [1] 43/8 vagaries [1] 97/1 valid [1] 72/4 value [1] 6/24 variance [1] 61/19 variances [1] 123/8 variation [2] 117/15 117/20 variations [1] 118/1 varied [1] 3/14 variety [1] 57/16 various [1] 124/8 vast [3] 127/25 133/9 159/24 vastly [1] 77/22 veered [1] 118/21 verb [1] 100/2 verbatim [1] 120/21 verdicts [1] 104/21 verification [3] 88/14 88/16 89/5 verified [1] 110/21	W wait [9] 15/21 54/5 117/10 150/13 152/20 152/20 156/5 156/5 156/5 waiting [1] 122/17 walk [1] 143/13 walking [1] 14/1 want [58] 3/5 3/19 7/10 8/1 11/13 16/6 18/2 18/18 44/20 48/23 53/23 60/25 64/18 66/5 66/24 66/25 67/19 74/6 74/25 77/7 80/20 80/20 81/11 81/20 81/21 81/22 91/12 91/20 96/23 98/14 99/8 101/1 102/18 103/11 105/24 106/5 107/2 107/6 107/11 115/23 129/10 131/23 134/5 135/8 137/16 143/19 144/11 146/13 147/6 155/22 156/2 156/10 156/10 157/24 158/8 161/1 161/4 161/5 wanted [7] 4/12 60/8 81/6 92/10 96/2 114/24 156/14 wants [1] 37/13 warn [40] 14/4 14/5 14/7 14/10 14/15 19/2 23/15 31/25	

<p>W</p> <p>Webster [1] 100/1</p> <p>week [3] 40/20 40/23 161/15</p> <p>welcome [1] 80/13</p> <p>well [37] 3/19 3/24 6/7 6/25 9/15 10/25 12/23 13/2 14/8 19/9 19/23 32/5 37/9 38/23 48/18 49/16 50/3 69/24 72/2 73/9 77/18 80/5 93/12 93/25 94/2 100/1 109/9 110/11 111/14 118/25 121/23 132/21 136/20 137/5 140/22 145/1 161/19</p> <p>well-pleaded [4] 93/25 118/25 121/23 137/5</p> <p>went [9] 24/1 24/1 32/25 44/16 74/8 96/3 117/5 120/24 121/14</p> <p>were [51] 4/11 9/25 20/10 30/3 34/1 37/1 43/4 45/4 45/23 49/4 52/13 52/24 61/24 63/2 65/12 68/22 70/10 70/11 71/25 73/3 73/4 73/11 78/20 79/21 86/15 88/3 91/25 92/19 94/20 106/2 109/22 109/25 112/16 114/20 115/21 116/24 120/17 121/12 122/11 123/23 127/14 132/9 134/25 140/24 140/24 142/5 143/14 145/2 146/22 148/18 155/24</p> <p>weren't [3] 63/3 63/3 96/25</p> <p>WEST [4] 1/2 1/5 1/17 2/18</p> <p>WestLaw [1] 104/14</p> <p>what [99] 3/18 5/16 9/2 9/3 10/24 11/1 12/22 16/6 24/13 28/10 29/13 30/9 31/11 32/12 34/16 43/8 44/8 44/25 46/8 50/16 50/18 51/16 52/23 53/7 53/8 54/10 54/15 54/21 54/22 55/3 55/8 56/15 56/25 58/18 60/11 64/17 69/24 71/8 71/10 72/22 73/16 76/24 79/16 83/1 86/5 87/19 88/7 88/9 89/20 89/21 89/23 90/24 95/14 98/16 99/4 101/13 101/25 102/21 102/23 103/10 104/7 107/17 111/8 111/11 114/25 115/15 118/14 118/15 120/12 120/16 122/24 126/17 129/10 130/21 131/3 131/11 132/16 132/16 132/23 133/17 133/25 136/1 138/1 140/18 144/21 147/9 148/14 148/22 150/7 150/25 151/13 152/24 153/1 154/21 156/24 156/25 157/2 158/5 159/3</p> <p>what temperatures [1] 115/15</p> <p>what the [1] 9/3</p> <p>whatever [3] 81/25 109/25 112/18</p> <p>when [57] 4/1 4/21 6/22 10/8 10/20 23/25 24/18 24/20 24/24 28/8 29/1 29/18 29/20 30/13 31/12 31/22 32/8 35/5 37/11 46/5 54/4 63/19 73/3 73/4 78/11 81/7 86/22 95/9 100/10 100/11 100/12 101/11</p>	<p>101/17 103/19 104/5 104/10 104/21 106/13 107/6 113/21 114/14 119/8 119/11 125/17 131/2 131/10 131/20 133/1 134/3 138/17 139/17 150/11 150/13 151/13 151/19 157/11 161/15</p> <p>where [66] 15/14 22/3 24/21 25/6 26/1 26/2 26/24 27/9 31/18 46/9 53/17 53/22 60/9 61/1 62/2 62/6 63/4 69/25 70/3 70/25 72/25 73/1 76/7 76/7 85/6 88/1 88/1 91/10 92/1 92/5 98/24 98/25 100/11 102/14 102/24 110/3 111/22 113/5 113/6 113/9 114/3 115/3 116/17 122/15 123/10 123/13 124/3 128/19 129/24 130/19 131/10 142/5 142/24 144/2 146/10 150/17 152/17 152/25 154/3 157/23 157/25 158/13 158/20 159/9 160/1 161/16</p> <p>where FDA [1] 128/19</p> <p>wherein [1] 123/23</p> <p>whether [21] 5/9 7/11 43/22 55/10 77/19 80/20 81/8 81/21 81/22 84/10 89/17 104/1 104/19 109/11 125/18 126/23 141/5 141/6 141/24 143/24 156/20</p> <p>which [86] 3/12 11/8 13/16 15/7 16/15 16/18 17/7 20/24 21/14 22/1 24/15 27/21 29/9 30/13 31/4 31/24 32/5 47/13 49/9 50/7 51/10 51/24 56/10 57/16 61/20 62/15 64/14 65/17 65/20 65/24 67/6 67/16 71/8 71/11 73/13 75/22 76/5 80/14 81/8 84/12 86/25 87/25 90/6 90/10 90/16 91/21 94/19 95/2 98/15 100/10 104/7 105/10 106/24 107/18 116/13 117/21 118/16 118/22 120/15 121/7 123/2 124/22 126/14 126/20 127/19 127/24 131/3 131/5 131/7 131/13 131/16 133/8 135/17 140/16 141/8 146/5 147/16 148/2 149/14 151/1 153/3 153/22 158/14 159/6 159/14 160/10</p> <p>while [9] 3/11 13/7 40/16 51/10 57/5 71/16 85/1 86/11 144/3</p> <p>who [21] 9/25 15/22 21/18 37/12 67/7 69/1 75/23 80/4 80/10 83/22 91/6 93/6 94/10 97/18 97/24 101/15 101/16 105/23 108/1 116/10 125/10</p> <p>whole [2] 49/19 118/20</p> <p>why [27] 19/12 24/7 24/16 40/8 40/8 41/12 44/16 46/20 50/24 51/12 58/20 61/15 62/21 84/19 96/13 97/2 101/9 103/12 103/13 111/7 121/7 126/2 129/12 131/22 143/8 148/1 152/20</p> <p>wide [1] 144/18</p>	<p>wide-ranging [1] 144/18</p> <p>widely [1] 51/11</p> <p>will [91] 3/16 3/16 3/22 4/6 7/15 7/16 7/17 7/19 7/20 8/5 8/6 8/7 8/8 8/9 17/5 17/9 20/8 20/16 20/17 23/1 25/6 37/9 37/12 37/23 54/7 56/14 56/15 56/19 60/3 60/15 61/7 66/9 66/11 67/3 67/11 67/17 67/17 67/23 71/8 71/24 72/24 73/10 73/19 73/25 78/23 79/2 80/1 80/2 80/2 80/4 80/10 80/17 81/1 81/2 81/3 81/9 81/16 81/24 81/25 82/2 82/4 82/9 82/10 85/6 91/1 100/14 102/12 102/25 105/24 108/22 123/16 125/1 125/8 125/10 125/12 125/19 126/2 126/4 127/2 133/11 134/2 134/18 134/20 134/25 138/21 145/12 148/25 149/6 161/8 161/14 161/16</p> <p>willing [4] 94/23 100/8 120/4 121/25</p> <p>win [1] 25/23</p> <p>window [1] 156/23</p> <p>wisely [1] 144/15</p> <p>wish [1] 152/15</p> <p>within [19] 4/25 11/2 12/9 25/19 40/5 46/12 47/21 58/25 59/8 59/18 88/17 105/4 113/20 119/25 120/3 141/22 155/11 156/22 157/3</p> <p>without [13] 36/9 42/5 46/23 52/4 70/4 77/4 91/15 94/19 97/5 100/14 104/2 111/18 111/18</p> <p>won't [6] 9/14 23/1 69/24 79/6 82/3 155/1</p> <p>Wonderful [1] 125/25</p> <p>wondering [1] 129/7</p> <p>word [6] 15/9 26/18 99/4 99/6 99/23 100/22</p> <p>words [20] 14/24 15/1 26/10 26/20 28/14 28/21 50/8 52/23 83/20 85/14 86/15 104/14 104/18 105/8 105/10 108/7 111/8 122/14 153/15 157/8</p> <p>work [4] 6/22 77/5 133/21 160/8</p> <p>worked [1] 3/24</p> <p>worker's [3] 102/14 109/16 109/17</p> <p>working [1] 83/25</p> <p>works [2] 129/11 129/12</p> <p>world [1] 84/20</p> <p>worth [5] 23/18 63/15 113/15 127/14 138/23</p> <p>would [161] 3/6 4/7 4/10 5/3 14/1 18/4 18/5 18/11 19/16 19/17 19/24 20/5 20/10 20/12 20/13 21/9 23/13 23/16 26/13 27/13 32/17 34/4 37/3 37/4 38/16 39/20 40/7 40/9 40/14 40/15 40/15 40/19 40/20 40/22 41/1 41/5 41/9 41/12 41/19 41/20 42/7 42/25 46/18 46/24 47/7 47/12 47/13 48/1</p>
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-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

W would... [113] 48/6 48/7 49/1 49/6 49/17 51/10 51/16 52/15 52/22 53/13 53/18 54/12 54/15 54/22 55/4 55/10 55/12 55/23 56/9 56/25 58/11 58/20 59/24 60/22 61/1 61/12 61/21 64/3 65/12 65/16 67/4 67/10 71/20 73/13 76/3 77/11 77/18 78/7 78/10 78/18 83/14 86/22 86/25 92/6 92/20 93/11 93/16 95/4 101/3 105/15 106/23 108/18 109/23 109/24 110/1 110/3 110/24 111/8 112/6 112/12 112/12 112/19 113/2 114/8 115/3 116/1 117/25 119/21 120/12 121/14 124/13 124/15 124/21 124/22 125/4 125/11 125/13 127/19 141/14 141/17 141/18 142/1 143/7 143/7 147/24 148/5 148/13 148/16 149/3 149/4 151/5 152/16 152/24 154/9 154/12 154/12 154/13 154/14 154/15 154/15 155/13 157/18 157/18 157/19 157/25 158/1 158/13 158/17 158/22 158/22 159/1 159/25 160/9 would sidestep [1] 127/19 wouldn't [11] 41/12 47/23 60/22 61/15 73/12 78/18 79/21 108/16 122/18 155/12 158/1 write [1] 68/7 written [10] 3/7 3/13 21/14 62/14 63/13 64/13 65/21 69/20 72/18 72/22 wrong [14] 25/4 46/12 96/25 97/6 97/21 98/2 103/13 107/16 107/17 109/18 110/4 117/8 150/25 151/2 Wyeth [4] 11/6 36/7 139/8 139/20	158/21 YOO [10] 1/19 7/17 7/23 8/6 37/20 38/8 39/5 54/4 54/11 55/20 York [2] 1/17 32/6 you [333] you specified [1] 158/14 you'd [1] 37/11 you're [1] 93/14 your [259] yourself [2] 6/15 66/18 yourselves [4] 7/10 80/18 81/20 105/24	
Y Yasmin [1] 17/21 Yaz [1] 17/21 year [6] 19/13 19/14 22/23 75/18 76/14 78/8 years [9] 10/13 10/14 13/5 23/20 24/3 24/18 29/7 95/18 98/8 yes [44] 5/13 7/22 7/25 23/9 38/8 38/19 39/5 39/8 39/14 42/15 45/22 47/11 48/1 48/22 54/3 54/9 54/10 55/17 67/2 81/13 101/3 106/20 107/11 108/12 110/5 111/9 112/18 113/2 114/24 115/24 120/10 121/11 124/15 137/7 138/13 143/21 145/20 145/24 147/23 148/9 155/8 155/16 157/6 157/9 yesterday [8] 4/21 9/11 9/24 19/21 80/8 82/22 83/10 97/11 yet [9] 24/5 31/19 51/5 51/8 77/17 104/7 114/18 115/16	Z ZANTAC [41] 1/4 3/3 23/19 23/23 83/12 83/24 84/3 84/11 84/14 84/17 85/18 108/7 108/10 108/15 108/19 110/2 110/4 111/3 111/6 111/24 112/7 113/11 115/10 122/14 126/15 126/15 127/6 127/8 128/12 128/15 129/1 130/5 132/2 132/3 132/6 132/8 132/20 132/20 146/11 153/15 155/24 Zantac or [1] 84/11 Zantac's [1] 110/4 zero [2] 2/9 150/2 Zoom [4] 1/9 3/24 4/3 80/7 zooming [1] 23/18	